Health Sector Resilience Checklist for High-Consequence Infectious Diseases—Informed by the Domestic US Ebola Response

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INTRODUCTION

Patients with Ebola Virus Disease (EVD) were treated in five US communities during the 2014-2016 epidemic in West Africa. Many more US communities were involved in monitoring travelers from affected countries and other individuals with various levels of possible Ebolavirus exposure. In some cases, these monitored individuals required medical care necessitating the implementation of precautions similar to those needed for actual EVD patients. Extraordinary measures were required to respond to these patients (whether actually or just potentially infected with Ebolavirus) and the potential public health threat that they posed. There are important lessons to be learned from the lived experience of individuals who were involved in the response to patients with confirmed and potential EVD in the United States, and communities that face high-consequence infectious disease (HCID) events in the future would benefit from awareness of those lessons. To that end, the purpose of this project was to develop an evidence-informed checklist that outlines action steps for medical and public health authorities, in partnership with nongovernmental organizations and private industry, to assess and strengthen the resilience of their community's health sector in the face of EVD or other HCIDs.

For the purpose of this project, we define HCIDs as having all of the following characteristics:

- Novel—or at least very rare—in the affected community
- Moderately to highly contagious (by whatever route), at least during some stage of the disease
- Moderately to highly lethal
- Not easily controllable by medical countermeasures or non-pharmaceutical interventions
- Causes exceptional public concern

Examples include: viral hemorrhagic fevers (e.g., Ebola, Marburg, Lassa), smallpox, SARS, MERS, and H5N1 influenza A.

The checklist is intended to apply to isolated cases or limited outbreaks of HCIDs. In a pandemic or widespread outbreak, the issues and recommendations may be substantially different.

The principal aim of this project was to develop evidence-based recommendations to enable communities to build health sector resilience to events involving HCIDs based on the domestic response to confirmed cases of EVD in the United States. This is a companion project to a recent health sector resilience checklist for natural disasters based on New York's experience with Hurricane Sandy.[1] For the purpose of this research, we defined the health sector rather broadly—including healthcare systems and facilities, public health, emergency medical services (EMS), public and private diagnostic laboratories, state and local government (e.g., elected officials), law enforcement, and academia. The health sector also includes community-based organizations that support these formal entities and represent the individuals who receive services from them. This broad definition is intended to generate, to the extent possible, comprehensive recommendations and to encourage cross-sectoral collaboration in planning, preparedness, response, and recovery operations. We also define health sector resilience very broadly, including actions taken before,

during, and after the event as well as existing characteristics and attributes of the community that preserve public health and healthcare delivery under stress and contribute to the rapid restoration and/or adaption of normal health sector functioning after the onset of a disaster. This research endeavored to move beyond official published guidance from state and federal agencies to learn directly from the individuals involved with response planning and operations. We believe that these individuals can, based on their personal experiences and expertise, provide vital insight into the effects of official guidance and identify areas where official guidelines were insufficient or non-existent or where operational challenges conflicted with official guidance.

Because relatively few major events in the United States have involved HCIDs, the domestic response to confirmed cases of EVD provided a unique opportunity to learn directly from those individuals involved in the response in order to identify unique challenges and lessons learned that could be directly applicable to US health sectors. Ultimately, this research produced a health sector resiliency checklist that provides actionable recommendations and highlights specific issues that require proactive efforts to address but do not necessarily have a universal solution.

While every infectious disease event, particularly those involving HCIDs, will inherently have its own unique challenges—depending on the pathogen, length of advance warning, socioeconomic and political factors, and many other variables—the findings from this research can provide general insight into the issues present in many infectious disease responses and, furthermore, elucidate particular challenges posed by HCIDs. These recommendations, and the associated checklist, cannot possibly encompass every challenge, but they can be used to inform state and local health sector leadership of the types of issues they may face in preparing for and responding to infectious disease events and highlight prospective problems that they may not otherwise anticipate. These leaders can then proactively address these issues before the onset of an event in order to improve the overall resiliency of their health sector and community to HCID events.

West Africa Ebola Epidemic (2013-2016)

In December 2013, an Ebola outbreak began in Guinea—near the border between Liberia and Sierra Leone—that would quickly grow to become the largest Ebola epidemic in recorded history.[2] The outbreak was reported to the World Health Organization (WHO) in March 2014,[3] and the epidemic eclipsed all previous Ebola outbreaks by June.[4,5] Lasting through 2015 and into 2016, the epidemic resulted in more than 28,000 cases and 11,000 deaths in Guinea, Liberia, and Sierra Leone, the countries hit hardest by Ebola.[6] Additional cases were reported in seven other countries, including the first recorded transmission of Ebolavirus infection outside of Africa.[7,8]

In August 2014, the United States responded to its first cases of EVD when two American healthcare workers, Kent Brantly and Nancy Writebol—infected in Liberia while providing clinical care to EVD patients—were transported to the United States for advanced treatment. Both patients were cared for in a specialized treatment and containment facility at Emory University Hospital in Atlanta, Georgia,[9] and both recovered and were discharged later that month.[10] Emory's Serious Communicable Disease Unit (SCDU) was established in 2002 with

support from the US Centers for Disease Control and Prevention (CDC), but these were the first EVD patients treated by the Emory University team.[11] The arrival and treatment of these two patients received considerable national media attention—including aerial coverage of their transport to Emory—and heightened concerns nationwide about the domestic threat from Ebola. Emory University also successfully treated Ian Crozier, another humanitarian clinician infected in Sierra Leone, in September 2014 as well as Amber Vinson, a nurse infected at Texas Health Presbyterian Hospital Dallas, in October 2014.[12,13]

The University of Nebraska Medical Center (UNMC) in Omaha received its first EVD patient in September 2014. Richard Sacra, a physician infected in Liberia, was treated at specialized facilities in the Nebraska Biocontainment Unit (NBU) and recovered after several weeks of intensive clinical care.[14] The NBU was established in 2005, and like Emory, this was their first experience treating an EVD patient.[15,16] UNMC also treated two other EVD patients—photojournalist Ashoka Mukpo and physician Martin Salia—in October and November 2014, respectively.[17,18] In addition to confirmed cases of EVD, UNMC also hosted several individuals with high-risk exposures to Ebolavirus, housing and monitoring them to ensure that they would have immediate access to advanced medical and containment facilities in the event that they developed symptoms of EVD and required rapid diagnosis and treatment.[19,20]

The first domestically identified case of EVD occurred in late September 2014. Thomas Eric Duncan, was infected in his home country of Liberia and then traveled to Dallas, Texas while the disease was in the incubation phase. Duncan arrived in the United States on September 20 and developed symptoms on September 24. He was seen in the emergency department at Texas Health Presbyterian Hospital Dallas on September 25 for a fever. Timelines of this visit—compiled weeks after the fact—indicate that information regarding Duncan's recent travel history was not adequately collected or utilized by the hospital staff. Duncan was discharged several hours later with a diagnosis of sinusitis.[21] Duncan was transported by ambulance back to Texas Health Dallas two days later and diagnosed with EVD.[22] Unlike Emory and UNMC, Texas Health Dallas did not have a dedicated biocontainment unit. An intensive care unit was evacuated of its patients, and Duncan was placed in isolation there. Despite intensive clinical treatment, Duncan died on October 8, 2014.[23]

The arrival of a previously unknown case of EVD escalated Ebola fear in the United States to a frenzy, fueled by reports that the patient was initially misdiagnosed and sent home as well as contentious rhetoric from politicians embroiled in heated midterm elections. Compounding this fear was the fact that two nurses who treated Duncan at Texas Health Dallas became infected with Ebolavirus as well. On October 10, Nina Pham developed a fever, and laboratory analysis on October 11 confirmed Ebolavirus infection. Amber Vinson tested positive for Ebolavirus infection on October 15.[24] Adding to the nation's anxiety, during Vinson's incubation period, she flew to Cleveland, Ohio and back to Dallas prompting significant reaction in Ohio, much of which was based on uninformed fear rather than science.[25] Both nurses were initially treated at Texas Health Dallas. Nina Pham was then transferred to the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland for the completion of her treatment, and Amber Vinson was transferred to

Emory.[26] Both nurses recovered and were discharged later that month.[27] The tragic death of Duncan and the associated infections of Pham and Vinson drew negative attention to the CDC's statements that any hospital was capable of caring for an EVD patient and contrasted the failures in Dallas against the successes of dedicated facilities at Emory, UNMC, and NIH.

On October 23, 2014, Craig Spencer, a physician who had recently returned from treating EVD patients in Guinea, reported a fever and was hospitalized at NYC Health + Hospitals/Bellevue in New York, New York. Unlike Duncan, Spencer was subject to enhanced returning traveler screening at JFK airport and was identified as being at elevated risk for EVD upon his arrival in the United States. As a result, Spencer self-monitored his condition with twice-daily temperature checks. When Spencer recognized his fever, he immediately notified Médecins Sans Frontières (MSF), the organization with which he worked in Guinea, and the New York City Department of Health and Mental Hygiene in order to begin the process of isolating and transporting him to Bellevue.[28,29] Like Texas Health Dallas, Bellevue did not have a purpose-built biocontainment unit; however, as we learned from key informant interviews, the hospital and city had already been planning for what they viewed as the inevitable arrival of an EVD case in New York. In response to Ebola, Bellevue developed the Special Pathogens Unit (SPU) in order to provide specialized care to HCID patients. When activated, the SPU takes over an existing negative pressure unit—initially designed in the 1990s for AIDS and tuberculosis patients—that can return to normal operations once it is no longer required by the SPU.[30]

Immediately after the announcement that Spencer was admitted to Bellevue and diagnosed with EVD, media concern skyrocketed regarding his activities in the days leading up to the onset of his symptoms. Spencer reportedly traveled using the New York City Subway and Uber; visited a local park, coffee shop, bowling alley, and restaurant; and went for a jog.[28] Extraordinary measures were taken by the city and business owners to inspect and sanitize the businesses Spencer patronized—despite assurances from health officials that this was unwarranted—as well as his apartment.[31,32] In the rush to calm fears, city officials failed to verify the credentials and permits of the company hired to clean Spencer's apartment, leading them to hire a firm without sufficient experience or expertise to conduct cleanup and decontamination operations.[33] In addition to the Ebola response activities, on October 24—the day after Spencer self-reported his fever—the New York and New Jersey state governments announced and implemented enhanced screening and quarantine policies, including a mandatory 21-day quarantine for all healthcare workers who had treated EVD patients.[34] That afternoon, Kaci Hickox, a nurse returning from West Africa, arrived at Newark Airport in New Jersey and was immediately placed under mandatory quarantine at a nearby hospital. Despite being symptom-free and testing negative for Ebolavirus infection, Hickox was quarantined for several days in a tent outside the hospital until the state of New Jersey relaxed their quarantine policy, at which time she was released.[35] These extraordinary actions, for which there was little supporting scientific evidence, were justified to the public as being taken "out of an abundance of caution."

Ultimately, eleven cases of EVD were treated at medical facilities in the United States, four of which were diagnosed domestically and nine of which survived.[36] In addition to the lone patients

in Dallas and New York, four patients were treated at Emory, three were treated at UNMC, and two were treated at NIH. Because experience in treating and managing the response to cases of HCIDs in the United States is relatively limited, the lessons learned from these EVD cases could prove invaluable to other communities seeking to bolster their resilience to these types of diseases. This research seeks to understand the experience of handling confirmed cases of EVD in Atlanta, Dallas, New York, and Omaha; identify challenges and solutions, particularly for unanticipated issues; and provide a checklist that can be utilized as a baseline tool to improve health sector resilience for similar infectious disease events.

To improve healthcare response, the CDC, in collaboration with the Department of Health and Human Services Assistant Secretary for Preparedness and Response (ASPR) and State and local partners, established a Tiered Hospital Network for Ebola with Frontline Healthcare Facilities, Assessment Hospitals, and Ebola treatment Centers.[37]

There are currently a number of national and international efforts, such as the National Ebola Training and Education Center (NETEC), but many of these focus specifically on developing clinical treatment guidelines for EVD or improving preparedness and response capabilities for biocontainment units. This research project, however, addresses the health sector more broadly—including healthcare, public health, state and local government, and community outreach—in order to build resilience, encompassing preparedness and response for a range of health-related entities as well as identifying sustainable actions designed to maintain operational capacity throughout the response and rapidly return to normal operations.

METHODS

Literature Review

Peer-reviewed publications, media reports, commentary, after-action reports, and other pertinent documents related to the domestic impact and management of the West Africa Ebola epidemic from 2014-2016 were reviewed. PubMed was utilized to identify peer-reviewed publications using the search terms provided in Table 1 combined with locations of interest (also in Table 1). Additionally, Google searches (including Google News) were conducted to identify relevant news articles and commentary regarding domestic EVD cases. Terms utilized for these searches include those from Table 1 as well as additional terms specific to each location (Table 2). Finally, additional searches were conducted as necessary in both PubMed and Google to further investigate specific topics identified through the primary searches. A total of 90 articles were included in the final literature review, which helped identify prospective interview participants and inform the salient themes that would be discussed during the interview process.

Table 1- Primary PubMed search terms

Search Terms:		**Locations:**
assessment	healthcare/health care	Atlanta/Georgia
communication	hospital	Dallas/Texas/Presbyterian
community/public	nurse	New York/Bellevue
emergency room/department	PPE/personal protective equipment	Omaha/Nebraska
EMT/emergency medical technician	recovery	Bethesda/Maryland/NIH/National Institutes of Health
Ebola	resilience	Cleveland/Akron/Tallmadge/Ohio
engagement	response	
health department	training	

Table 2- Additional Google search terms

Georgia	**Texas**	**New York**	**Nebraska**	**Maryland**	**Ohio**
Atlanta	Dallas	Bellevue	Omaha	Bethesda	Cleveland
Emory	Texas Health Presbyterian	Craig Spencer	Rick/ Richard Sacra	NIH/National Institutes of Health	Akron
Kent Brantly	Thomas Eric Duncan	subway/Uber	Ashoka Mukpo	Nina Pham	Tallmadge
Nancy Writebol	Nina Pham	bowling alley/restaurant	Martin Salia		Solon
Amber Vinson	Amber Vinson	park			Frontier Airlines 1142
Ian Crozier	school closing	clean			fly/flight
	Belton				school closing
	clean				wedding/dress

Key Informant Interviews

Selection and recruitment of participants

Semi-structured interviews with key informants were conducted from February to November 2016 in order to identify factors that contributed to or impeded health sector resilience during the US response to confirmed cases of EVD. Prospective interviewees included individuals known by the project team to have been directly involved in managing confirmed EVD cases in Atlanta, Dallas, New York, and Nebraska as well as individuals and organizations involved with health care, public

health, and other vital functions identified through the literature review. A snowball sampling technique—in which interview participants recommended colleagues or other contacts that would have a unique perspective on the Ebola response—was also utilized to identify additional prospective participants. Prospective interviewees were selected to represent Atlanta, Dallas, New York, and Omaha and included individuals who worked in health care; local, state, and federal public health; law; local and state emergency management; academia; local and national media; and local and state government during the US Ebola response. In total, the project team interviewed 73 participants from four cities that treated confirmed cases of EVD (Atlanta- 17, Dallas- 22, New York- 13, Omaha- 18, CDC- 3) representing a variety of fields pertinent to the US Ebola response.

Data collection and analysis

For the key informant interviews, a semi-structured interview outline was developed based on themes identified in the literature review in addition to the study team's prior knowledge and experience in the fields of infectious disease, clinical/critical care, and public health emergency preparedness. A total of 67 individual and group interviews (73 total participants) were conducted via telephone. All interviews were conducted on a not-for-attribution basis to encourage frank and honest discussion. Each interview was attended by at least two study team members, including the primary interviewer and a note taker, and lasted approximately 45 minutes. Each interview was assigned a unique, random alphanumeric identification code to ensure confidentiality, and with the permission of the participant, each interview was recorded and transcribed to facilitate thematic analysis.

Regular meetings were held by the study team throughout the interview process to discuss recurring and emergent themes, which helped to direct discussions in future interviews and ultimately inform the thematic coding rubric. To conduct the qualitative thematic analysis, each transcript was coded using QSR International's NVivo 11 Software. The transcripts from five interviews were co-coded by three members of the project team to assess the quality and inclusiveness of the identified themes and ensure that the team members consistently applied the thematic rubric. After ensuring that each team member agreed upon the context and meaning of each theme based on the rubric, the remaining interview transcripts were coded by a single team member to ensure consistency within the coding. The results of the thematic analysis informed the recommended actions included in the checklist.

Focus Groups

Focus group meetings were conducted in New York and Dallas to further investigate certain themes identified in the key informant interviews. The focus groups were conducted in person between members of the project team from the Center for Health Security and select study participants and were two hours in duration. The New York focus group was conducted in December 2016, and the Dallas focus group was conducted in January 2017. Focus group participants held various positions in the health sector, including emergency management, public

health, clinical health care, EMS, and local government. For each focus group, the study team developed a set of key issues that warranted further discussion based on themes identified during the key informant interviews. The focus groups were open-ended discussions facilitated by the study team, and each meeting was recorded with permission of the participants in order to support further analysis as necessary. Four members of the project team attend each focus group, with multiple team members taking notes. As with the participant interviews, the focus group meetings were conducted on a not-for-attribution basis.

Expert Advisory Group Meeting

An expert advisory group meeting was conducted in January 2017 at the Johns Hopkins Center for Health Security[i] (Baltimore, Maryland) to discuss the preliminary findings of this research. Advisory group participants included subject matter experts in the fields of infectious disease and public health emergency preparedness with whom the project team has existing relationships, project interview participants, others with roles during the US Ebola response, and potential end users of the checklist. Each participant was provided an advance copy of the preliminary findings one week prior to the meeting, and participants were asked to comment on the completeness, accuracy, relevance, and relative importance of each finding. The expert advisory group meeting was five hours in duration, and all discussion was conducted on a not-for-attribution basis. Audio of the meeting was recorded with permission of the participants to assist in revising the checklist.

Limitations

While significant effort was taken to ensure robust and potentially generalizable results from this project, this study was subject to several limitations. First, the experiences of the study participants may not be representative of many other localities. Three of the locations involved in this study (Atlanta, New York, Omaha) have facilities designed specifically for the treatment of HCIDs such as EVD. In lower resource areas—or even well-resourced healthcare settings without specialized treatment and isolation facilities—the response to a similar infectious disease event may unfold very differently, potentially with an adverse effect on the ability of the health sector to respond and recover.

Additionally, because this study was conducted 1-to-2 years after the domestic Ebola response, there is potential for recall bias. Many of the participants, particularly those directly involved with patient care, indicated that the intensity of the response and the gravity of the events made it easier to vividly remember details, but others were unable to provide detailed information about some aspects of their experience. The interview participants were also not randomly selected and are not a representative sample of all those involved in the Ebola response across the United States. Because the majority of prospective participants were identified through articles found in

[i] The project was initiated at the UPMC Center for Health Security; however, the Center for Health Security transitioned affiliation to the Johns Hopkins Bloomberg School of Public Health during the final weeks of the project.

the literature review, our study population skewed toward higher-profile responders. The inclusion of snowball sampling for the key informant interviews helped the project team identify additional colleagues and contacts of interview participants that were not prominent in local or national media or peer-reviewed literature and expanded the scope of experience for the study population.

Finally, the aim of this study was to identify themes that could strengthen health sector resilience during an infectious disease event. The collection and analysis of data was strictly qualitative, and no attempts were made to analyze the results quantitatively.

The University of Pittsburgh Institutional Review Board[ii] designated this research as "exempt" under §45 CFR 46.101(b)(2). This project was determined to be "not human subjects research" by the CDC Human Research Protection Office, and Paperwork Reduction Act requirements were determined to be non-applicable. This study was supported by federal funding through contract 200-2015-M-87759 "Health Sector Resilience Checklist for Highly Infectious Diseases."

FINDINGS AND DISCUSSION

The following are the most salient themes that emerged from the interviews and focus group discussions, and these findings were used to inform the recommendations in the checklist. The first set of findings below (Section 1) apply broadly to planning, preparedness, response, and recovery for HCID events, and the subsequent findings address more specific areas of focus that will likely be included in these types of incidents. These findings are intended to inform the universe of individuals who may be involved in preparing for the management of HCID events at the local and state levels. This includes clinicians across the healthcare delivery system, including EMS; public health practitioners; emergency managers and administrators for healthcare facilities, municipalities, and states; elected officials; and leadership and operators in a range of other agencies and organizations that may be involved in the response.

The context of these recommendations is a local case (or cases) of a HCID that has the potential to be an immediate and serious threat to the public's health and which may or may not be part of a larger epidemic; they are not intended to apply to more routine infectious diseases. Some of these findings may not have a corresponding recommended action, rather, they identify issues that might not otherwise be considered in advance of a HCID event. Finally, these findings may not be applicable for all pathogens or events; the mode of transmission, symptomology, infection and fatality rates, and available treatment and prevention options as well as the particular

[ii] This project was initiated at the UPMC Center for Health Security. Under an agreement between the University of Pittsburgh and the Johns Hopkins Bloomberg School of Public Health, the project remained under the purview of the University of Pittsburgh Institutional Review Board after the Center for Health Security transitioned its affiliation to Johns Hopkins, as all relevant data collection had been completed and the project was coming to a close.

relationships between healthcare systems, public health, and other agencies at the state and local levels will have an impact on many of these findings.

1 Overarching Issues

1.1 Preparedness

Finding: *An optimal response to a serious infectious disease outbreak is not possible unless there exists a robust and resilient public health and healthcare capacity.*

Well-established and maintained public health and healthcare infrastructure that can effectively manage a serious outbreak is vital for responding to HCID events. Public health preparedness funding has decreased steadily since its peak after 9/11,[38] but substantial and sustained funding at the federal, state, and local level is required to, among other things, hire and train staff, modernize information and communication systems, and facilitate coordination between relevant sectors in order to rebuild a public health infrastructure that can support response to a major outbreak. Additionally, highly trained and proficient healthcare personnel practicing proper patient screening and infection control measures on a daily basis can play a major role in limiting the scope and spread of HCID events well before they can gain a foothold in healthcare facilities or the community.

Partnerships between and among entities that may be involved in a response (e.g., EMS, public health, healthcare facilities and systems, law enforcement, airports) must be formed and maintained before the onset of an emergency event. This collaboration includes developing and exercising a framework for communication between agencies to enhance coordination and ongoing, active cooperation to progressively update and improve these frameworks in the periods between events. Additionally, as data collection and analysis systems (e.g., electronic health records) become more capable, developing and integrating data systems across entities in the health sector can improve collaboration and communication, particularly for infectious disease events. In many locales, these types of collaboration could be accomplished through Healthcare Coalitions (HCCs), and they may be supported by Memoranda of Understanding (MOUs), Mutual Aid Agreements (MAAs), working groups, consortia, or a number of other mechanisms.

1.2 Leadership

Finding: *At each location and at each level (i.e., facility, local, state, and federal), a single leader must be identified early in the response so that people—including responders, the public, and the media—know who is in charge.*

A formal incident command structure (i.e., Incident Command System [ICS]) should be implemented at each level (e.g., facility, municipality, county/region, state) so that roles and responsibilities are clear to all responders. In each organization, the role of Incident Commander may be assumed by a range of individuals, but regardless of who serves in this role, an infectious diseases expert should be designated as a top advisor during infectious disease events, particularly

those involving HCIDs, in order to help ensure that appropriate response activities and policies are implemented and build public confidence. Because HCID events involve an unfamiliar threat, they can result in additional fear and concern in the community. Having an expert advising the top-level response leadership, including local and state elected officials, can help reassure the public and political leaders that decision-making is scientifically sound.

Infectious disease preparedness efforts should be integrated across the entities expected to be involved in the response (e.g., government agencies/departments, healthcare delivery systems, non-governmental organizations) at the facility, community, state, and national level to improve a unified response to infectious disease emergencies. Establishing and developing relationships and identifying associated chains of command between these entities prior to the onset of an event is critical to ensuring efficient coordination during response and recovery operations.

1.3 Adaptive Resilience & Flexibility

Finding: *Established protocols that cover a range of event types (i.e., all-hazards approach) should provide a starting point for any response.*

Annexes for specific event types can supplement all-hazards plans to address needs unique to different types of incidents, but these will inherently not be able to cover every possible scenario—nor do they need to. Existing plans should be initially followed and then adjusted as events unfold. Knowledge, facts, and resulting guidance are likely to evolve during any incident response, especially those involving HCIDs. Response entities (e.g., healthcare facilities, public health departments, EMS organizations) should have a well-trained and exercised infectious disease response plan in place but also be ready to adapt it as necessary to fit the specific circumstances of the incident. Rather than developing wholly new plans or being locked into specific response protocols, response entities should develop and exercise nimble organizational processes that enable them to adapt existing plans to incorporate novel policies and operational procedures in the midst of a response in order to account for new information, uncertain science, and/or differences in professional opinions. The 2014 domestic Ebola response represented one type of response infrastructure—tiered hospital network—which was implemented and adapted as more information became available. This exact command and response structure may not be suitable for other HCID events, but the process of adapting to event circumstances should be utilized for other infectious disease emergencies.

2 Governance and Coordination

2.1 Command Structure

Finding: *Local leadership is vital to implementing an effective response and recovery.*

The senior local government official (e.g., mayor, county executive/administrator) should be prepared to play a leading and highly visible role in the response, whether or not they are the designated Incident Commander. While local leadership may not necessarily have expertise in a

particular type of incident, they have the most accurate information about available resources and capabilities in their jurisdiction, and they have established relationships and necessary clout with relevant agencies and organizations. State and federal personnel play a crucial role in providing guidance and necessary resources, but local leadership should remain in command. For incidents that affect multiple local jurisdictions, regional or state leadership will be necessary to coordinate response activities across a larger geographic area.

Finding: *Responses to HCID events at each level (e.g., facility, municipal, state, federal) should utilize the same ICS structure that is used for other events/responses.*

Using the same general response leadership hierarchy and organization will foster consistency and efficiency. Specialized units/sections/branches/etc., however, will likely be needed to address specific requirements of infectious disease responses. Prospective Incident Commanders at all levels should have a clear understanding of the federal (e.g., CDC, EPA), state, and local roles in infectious disease emergencies (e.g., who is in charge and where authorities change depending on the particular issue). For example, federal agencies have limited authority for issues that are confined to one state but more authority for issues that cross state lines (e.g., EPA for interstate transfer of waste). Furthermore, public health needs to be better incorporated into emergency response activities—for a number of event types, not just infectious disease. In many cases, public health incident response activates separately, often before, the rest of the incident command structure. A fully integrated response improves cross-sectoral coordination and helps ensure that appropriate resources and information are efficiently transferred to support response decision-making and activities.

2.2 Expert Advice

Finding: *An expert advisory group can provide consensus recommendations to inform the response.*

During the US Ebola response, several states instituted governor-level task forces composed of a multidisciplinary group of subject matter experts, both technical and operational. The support of these expert groups not only improves the actions and polices implemented during the response, they also lend legitimacy to the decisions made by elected officials and response leadership, helping to increase public and media support. These groups can also provide much-needed expertise to help elected officials and response leadership address public and media inquiries.

Finding: *Many federal agencies, like the CDC, can rarely provide support unless explicitly requested by the state; however, local leaders may not have the expertise or experience to know what kinds of resources are needed or available.*

Such knowledge may exist at the state or federal (e.g., CDC) level, but local and state leadership need to know to request it. Local and state officials should request assistance as early as possible and be explicit about what help they need. Even if the initial request is potentially excessive, local leaders should “ask early and ask big;” it is easier to send back resources that are not needed than

to make subsequent requests for additional support. These requests for external support should be made through a single point of contact (e.g., Incident Commander) to ensure that the resources received are appropriately distributed. Simultaneous requests from multiple agencies and/or facilities can potentially result in resource shortages (e.g., PPE) where they are needed most.

Finding: *Requesting capabilities rather than specific resources is a way to get what is needed when local leadership may not know precisely what resources are required or available.*

It is often easier to articulate the types of tasks or activities that are needed than it is to determine the specific resources needed to accomplish them, and this tactic allows local leadership to rely on the expertise and experience of leadership external to the response (e.g., from state and federal agencies) to identify the required resources. Additionally, when state and local officials request support, they should know to also ask, "What else should I be asking for?" This further enables experts who are external to the response to recommend additional resources and response actions that the local response may not have considered.

3 Communication and Community Context

3.1 Fear-Based Reactions

Finding: *Fear of the unknown, particularly in the context of changing and, often, conflicting information, can trigger highly emotional public responses.*

An unfamiliar and highly lethal disease, EVD elicited strong public reactions, grabbed headlines in traditional and social media, and prompted overreach by uninformed and/or attention-seeking authorities during the midterm election cycle. Shunning of individuals who were thought (often incorrectly) to have been potentially exposed to Ebolavirus was widespread, especially early in the response. Stigmatized populations included individuals from affected countries, international travelers, and healthcare workers from affected facilities. Stigmatization occurred among coworkers at affected hospitals and extended to healthcare workers' family members in settings like schools and daycare centers.[39] As noted by respondents, information campaigns and robust public outreach by trusted and influential community leaders and experts helped to mitigate the acute fear and, to a lesser degree, counter the stigmatization. On the other hand, some authorities invoked "an abundance of caution" in taking steps not supported by science in an attempt to assuage public fear. These actions were taken because of perceived uncertainty in the science or to demonstrate that the officials were "doing something." Viewed as relatively harmless by those who implemented them, the very fact that these actions were taken gave the impression to many that they must have been warranted, thereby unintentionally amplifying the perceived danger posed by Ebola.

3.2 **Public Trust**

Finding: *An effective HCID response depends on public trust in governmental and health institutions.*

During an outbreak, efforts to treat sick people and to interrupt disease transmission take place in the context of the larger community. Their success hinges, in part, on whether local residents have confidence in hospitals, health departments, and other response organizations. In non-crisis periods, health officials and providers should build up stores of public trust through a "good neighbor" policy and mutual understanding. Treatment hospitals, for instance, can foster public faith in their ability to manage HCID patients by identifying and responding to community health needs. This can include active engagement to improve overall community health (e.g., via a Community Health Needs Assessment [CHNA]) and proactively publicizing the capabilities of their biocontainment units and the larger healthcare facility and network through mechanisms such as public lectures, tours, and media engagement. Facilities with biocontainment units that engaged the local community prior to the Ebola response reaped the dividends of this transparency during the crisis.

Health departments can similarly strengthen public trust in advance of a HCID event via community engagement, ranging from foundational activities like CHNAs and health improvement planning to preparedness partnerships with community- and faith-based organizations (CFBOs), especially those with roots in underserved, vulnerable populations. CFBOs can assert member interests in emergency planning, amplify and translate public education and crisis communication (including information on unfamiliar isolation and quarantine concepts and practices), and provide mental and material support to affected individuals in an outbreak. During the Ebola response, for instance, numerous local nonprofit organizations assisted quarantined individuals by locating housing and providing essentials like groceries.

Resources are available to support recommended community engagement and collaboration efforts:

Association for Community Health Improvement (ACHI). Community Health Assessment Toolkit. Available at http://www.assesstoolkit.org/.

Association of State and Territorial Health Officials (ASTHO). At-Risk Populations and Pandemic Influenza: Planning Guidance for State, Territorial, Tribal, and Local Health Departments. Available at http://www.astho.org/Infectious-Disease/At-Risk-Populations/At-Risk-Populations-and-Pandemic-Influenza-Planning-Guidance/.

US Centers for Disease Control and Prevention (CDC). Community Health Assessment & Health Improvement Planning. Available at https://www.cdc.gov/stltpublichealth/cha/index.html.

National Association of County and City Health Officials (NACCHO). Mobilizing for Action through Planning and Partnerships (MAPP). Available at http://archived.naccho.org/topics/infrastructure/MAPP/index.cfm.

Santibanez S, Siegel V, O'Sullivan M, Lacson R, Jorstad C. Health communications and community mobilization during an Ebola response: partnerships with community and faith-based organizations. *Public Health Reports*. 2015;130(2):128-133. Available at http://journals.sagepub.com/doi/pdf/10.1177/003335491513000205.

3.3 Crisis & Emergency Risk Communication

Finding: *Public trust depends on effective crisis communication.*

Timely delivery of credible and actionable information during an outbreak serves as a powerful antidote to overwhelming fear and anti-social behaviors and helps to mobilize the whole community for epidemic control purposes. In an infectious disease crisis, people are hungry for information on what responders know, what government is doing, and how individuals can protect themselves and their families. State and local health departments and healthcare facilities should develop a strong crisis and emergency risk communication capability to meet the information needs of the broader community and a diverse healthcare workforce during an outbreak. Such capability includes trained spokespersons able to discuss risk in the context of uncertainty (i.e., what is known and not known and what is being done to fill the gaps). These spokespersons should have a strong communication science base that enables them to identify what information people want or need, what formats and which dissemination channels to use, how to craft culturally competent messages, and how to identify and enlist trusted intermediaries.

During the US domestic Ebola response, strong coordination and communication between healthcare and local and state health departments enabled a more successful response, as did prompt public communication that included opportunities for community members and the media to ask questions (e.g., town hall meetings, social media, guest spokespersons, hotlines). Monitoring social media helped to rapidly identify and dispel rumors, correct misinformation, and respond to priority topics for the public. Going forward, health departments should engage in communication planning with hospitals that are likely to respond to HCID events, particularly with respect to timing for the release of information and pre-scripted messages for dissemination to hospital staff and the public. Experience during the Ebola response indicated that local media are committed to their community and generally look for a positive story. Conversely, participants indicated that their interactions with national media outlets were less beneficial and that some national media representatives seemed more interested in framing reports in terms of a pre-established narrative or finding a compelling story than reporting on the events themselves. Local media are very sensitive to being "spun" or misled, however, and communicating with local media early, often, and honestly can help foster accurate reporting. Coupled with scientifically unsubstantiated epidemic control measures, the phrase "an abundance of caution" conveyed mixed messages (i.e., that the actions taken were simultaneously warranted and unwarranted).

Instead of using this shorthand phrase, when there is significant uncertainly, officials should be transparent about what is known and what is not and forthrightly explain their decision-making process based on potential benefits and risks. Comprehensive communication resources are available that address crisis psychology, message development, planning and communication strategy, traditional and social media engagement, and stakeholder and partner communication—including with vulnerable populations:

US Centers for Disease Control and Prevention (CDC). Crisis and Emergency Risk Communication. Available at https://emergency.cdc.gov/cerc/index.asp.

US Centers for Disease Control and Prevention (CDC). Planning for an Emergency: Strategies for Identifying and Engaging At-Risk Groups - A Guidance Document for Emergency Managers. Available at https://www.cdc.gov/nceh/hsb/disaster/atriskguidance.pdf.

US Centers for Disease Control and Prevention (CDC). Public Health Workbook to Define, Locate, and Reach Special, Vulnerable, and At-Risk Populations in an Emergency. Available at https://emergency.cdc.gov/workbook/pdf/ph_workbookfinal.pdf.

4 Public Health Issues

Finding: *Public health system structures vary widely between states and municipalities, and these differences must be taken into account during an infectious disease outbreak.*

Lines of authority and jurisdiction for various actions should be clear in advance of an event in order to prevent duplication of effort and ensure that the appropriate authority for these decisions rests with or is delegated to the Incident Commander. Some potential issues that could arise include determining which jurisdiction has public health authority (eg, municipal, county, state) or which governmental agency or official has authority to issue and/or enforce mandatory quarantine and isolation orders. Additionally, the scope of public health's responsibility and authority will likely vary by jurisdiction. For example, some public health departments operate or coordinate EMS, while other EMS systems are operated by independent departments, other departments (e.g., fire department), or private companies. Additionally, some health departments operate standalone clinics and hospitals that may or may not be equipped to treat patients with HCIDs. Public health will invariably be at the center of infectious disease event responses, particularly for HCID events, but coordination with a variety of other entities (e.g., healthcare delivery system, law enforcement) is critical to establishing an effective, multi-sectoral response. Coordination protocols should be developed and well exercised prior to the onset of an infectious disease event in order to ensure that the Incident Commander can make effective and efficient use of all available resources from across the relevant response entities.

4.1 Public Health Law

Finding: *Public health laws, particularly those involving quarantine and isolation orders, are complex.*

The authority for issuing and enforcing these orders may fall on leadership in different government agencies, and issuing or enforcing these orders may require actions by a number of different entities, including the judicial system. Elected and public health officials at the state and local levels need to be familiar with relevant public health and safety laws and policies prior to the onset of an event. Effort needs to be made in advance of a public health event—in close consultation with legal experts—to ensure that officials understand the scope and limitations of these laws and policies and to identify the individuals and agencies with associated authority and responsibility. These laws and policies need to explicitly include provisions necessary to address cases involving special populations (e.g., children, homeless individuals, mentally or physically challenged individuals, non-English speakers) to ensure that all affected individuals have access to due process and appropriate mechanisms for recourse.

4.2 Quarantine

Finding: *Quarantine laws and regulations are complex, vary by state, and are often not well understood*.

State guidelines, regulations, and legislation regarding quarantine should be as explicit and clear as practicable and be soundly based on scientific evidence. These state policies also exist within the context of federal quarantine regulations which authorize public health authorities at the federal level to implement prevention activities at US airports, seaports, railway stations, bus terminals, and other transportation centers. A CDC official may issue an order for apprehension, isolation, quarantine, examination, or conditional release of an individual based on "reasonable beliefs" that a person of interest may be infected with a quarantinable disease.[40] Quarantine policies should be limited in scope to the extent possible in order to avoid unnecessarily infringing on individuals' civil rights while still remaining effective as interventions. All quarantine policies, regulations, and legislation should be vetted in advance by experts in both public health law and practice to ensure their legitimacy, inform implementation mechanisms, and identify potential areas for challenge.

In addition to the prevention of disease transmission, quarantine guidelines and policies should have as a primary consideration the care of affected individuals. Factors such as legal counsel and due process (including expeditious processes to challenge quarantine orders); patient privacy; food, drink, and clothing (including personal and religious restrictions); adequate shelter (particularly for homeless individuals); mental health support; clinical care for unrelated medical conditions; recuperation of lost wages; care for family members and pets; and communication with family and friends need to be explicitly addressed. Additionally, planning and coordination with local law enforcement is required to ensure that, if necessary, law enforcement officials are able to provide security at the quarantine location in order to both protect the affected individual

and ensure that the individual complies with the provisions delineated in the issued orders. The challenges involved with quarantining individuals become increasingly difficult as the number of affected individuals rises. Events that require large numbers of individuals to be quarantined can quickly exceed the capacity of communities and health systems to manage them on an individual basis, and quarantine plans need to include provisions for conducting these activities on a large scale, including housing/shelter, security, and the scale-up of ancillary services. Finally, close coordination with EMS and the healthcare system is necessary to develop and implement plans for transporting the individual to an appropriate treatment or assessment facility in the event that he/she becomes symptomatic.

Because quarantine is not a commonly utilized intervention, the details of these plans are likely unfamiliar to many elected and appointed officials as well as the vast majority of the public. The creation of an advocacy group for quarantined individuals would be useful to provide proactive advice to policymakers on public health law and quarantine guidance during an incident response. A national network of experts in public health and civil rights law could provide elected and public officials with sound legal advice with respect to implementing and enforcing quarantine laws and policies and provide affected individuals with specialized legal counsel to ensure that they are treated properly and that their rights are protected, particularly with respect to due process and challenging issued orders.

The optics of quarantine are a significant challenge to manage, particularly in the midst of a response. Quarantine (and similarly, isolation) is, in and of itself, a public health intervention designed to prevent the spread of disease, not a punishment or sentence for criminal behavior; however, because it inherently involves restricting individuals' movement and freedom, it can easily appear this way. This holds particularly true if police or other officials are required to be on site to enforce the order. On the other hand, while the quarantine itself is not in response to criminal activity, the act of violating a quarantine order may constitute a criminal act. In light of these challenges, it is vital to establish a relationship with quarantined individuals and ensure that they fully understand the purpose of the quarantine and the explicit restrictions being placed on them as well as the services available to them and their rights regarding due process. Additionally, existing and trusted relationships with the public and media (particularly local media) can be beneficial to communicating the facts surrounding publicized quarantine events rather than potentially contradictory and damaging storylines.

In the course of our research, several participants discussed the desire to utilize "voluntary quarantine" when possible in order to avoid the need to issue mandatory quarantine orders. In these cases, individuals agreed to restrict their own movement and contact with others. On one hand, this process appears to expediently achieve the desired public health objectives while still respecting individuals' self-determination, and it models for the community a collaborative as opposed to a confrontational approach to epidemic control. On the other hand, the quarantine is not wholly voluntary. If an affected individual is given the option of "voluntary" or mandatory quarantine, an element of coercion applies and he/she has little choice in the final outcome (i.e., the individual is quarantined one way or the other). Additionally, there is no due process for

challenging a "voluntary quarantine." Without an official order in place, the quarantined individual may have limited or no ability to challenge the quarantine without incurring public backlash for reneging on his/her commitment. Various forms of "voluntary quarantine" were employed extensively during the Ebola response in the United States—mostly without incident—but the potential exists for both operational and legal complications.

4.3 **Monitoring Programs**

Finding: *Monitoring and tracking of potentially exposed individuals can reduce the need for quarantine, but these programs are extremely difficult and resource intensive to implement.*

In some responses, the unique characteristics of the event (e.g., mode of transmission, morbidity and mortality rates, disease severity) may necessitate tracking and monitoring certain individuals at risk of developing the disease—in order to rapidly respond in the event that they develop symptoms—without placing them under quarantine. Monitoring programs were utilized extensively in the United States during the domestic response to Ebola for several reasons. First scientific evidence clearly showed that infected individuals are not contagious—and therefore, did not warrant quarantine—until the onset of symptoms, specifically a fever that is readily identifiable through routine monitoring activities. Additionally, EVD has a well-defined maximum incubation period, after which it is highly unlikely that an infected individual will become symptomatic and infectious. Monitoring programs can help to rapidly identify newly symptomatic individuals and notify healthcare providers that monitored individuals have had potential exposure to the pathogen in question. In some cases, monitoring programs may include certain movement and travel restrictions that fall short of formal quarantine. Again, any movement restrictions imposed should have a sound basis in scientific evidence and be as limited in scope as practicable while still serving their purpose. In addition to helping public health and healthcare systems monitor at-risk individuals, these programs also provide a ready-made interface with the public health and healthcare system for individuals who may lack resources to do so otherwise. During the domestic response to Ebola, for example, many of the monitored individuals arrived in the United States with a limited local network of family and friends, and public health personnel provided access to a number of public health, healthcare, and social services. Because movement restrictions can limit an individual's ability to meet some of his or her daily living needs, planning for these needs is an important component of preparedness. Engagement with a range of community partners, including businesses, schools, charitable foundations, CFBOs, and mental health resources can provide a useful basis for addressing these needs and facilitate successful monitoring.[41,42]

In responses that necessitate the implementation of monitoring programs, state and local public health personnel must be clear and consistent regarding the metrics used to determine when individuals require monitoring as well as the details of the monitoring procedures. When case definitions for monitored individuals are developed—by local, state, or federal authorities—they must be based on scientific evidence and should be as limited in scope as practicable to prevent the violation of individuals' rights. The unique circumstances of each infectious disease event

need to be considered when developing these case definitions and for determining what, if any, monitoring requirements will be put in place. The most important factor to consider in these decisions is risk, both of transmitting the disease to others *and* of each individual being infected based on their individual exposure level. These risk assessments must be based on scientific evidence rather than public concern in order to ensure that appropriate interventions are implemented. Additionally, when there are federal guidelines for case definitions and monitoring requirements, states and municipalities need to understand and adhere to them consistently. Variations in case definitions between states or local jurisdictions or in how monitoring programs are implemented (including any applicable movement restrictions) undermine the guidelines and the scientific data on which these definitions and associated public health interventions are based. Finally, a one-size-fits-all management and monitoring plan may not be feasible, and authorities should be aware of the needs of special populations—including children, people with impaired cognition, non-English speakers, incarcerated populations, and homeless individuals. Protocols and resource plans that address specific individual or population needs should be implemented as necessary.

During situations in which monitoring of individuals is necessitated, it is important to establish a relationship with affected individuals. Conducting initial face-to-face meetings with these individuals enables public health personnel to establish a trusted relationship with them. In-person meetings provide an opportunity to explain monitoring requirements and movement restrictions to the individual as well as address any questions or concerns he/she may have. It is beneficial to provide monitored individuals with a simple mechanism with which to conduct required monitoring and check-in activities in order to enhance compliance and reduce the burden on the monitored individual.

Active monitoring can be accomplished through a variety of means, including face-to-face visits by public health personnel, phone calls, or video chats (e.g., Skype, FaceTime). Providing affected individuals with a dedicated cell phone or internet access as well as contact information and instructions can help facilitate good communication and cooperation during the monitoring period, particularly for those who may not have a cell phone or a strong local network of family and friends. Phones and the internet can facilitate active monitoring without face-to-face meetings (if appropriate), thus reducing the workload on public health personnel. Furthermore, online systems that enable individuals to enter their own monitoring information (e.g., temperature or other symptoms) can be used in situations in which a passive monitoring approach is appropriate. These mechanisms can limit the imposition on monitored individuals and help them take more control of their monitoring while also significantly reducing the workload on public health and healthcare personnel required to obtain this data compared to active monitoring programs.

Because monitoring programs may involve potentially sensitive personal or medical information, specific attention needs to be paid to data security. While passive reporting systems can be convenient, maintaining the safety of individuals' personally identifiable information and medical data is paramount. Security is also a concern for active and remote active monitoring programs.

Mechanisms like text messages and video chat (e.g., Skype, FaceTime) may not provide sufficient protection for patient data. Local and state health officials need to work closely with information technology and data security experts as well as legal counsel to identify and implement appropriate mechanisms to ensure data security, regardless of the type of monitoring program.

Monitored individuals may arrive from another jurisdiction, and local public health officials need to have a point of contact identified—ideally, prior to the onset of the event—to rapidly coordinate with other jurisdictions and ensure that monitoring activities are initiated and implemented properly. As was the case with the West Africa Ebola epidemic, the initial US cases for future HCID events may be imported from abroad, and some monitored individuals will likely arrive from outside the United States. Furthermore, if travel restrictions similar to those during the US Ebola response—resulting in all passengers originating in the affected area being routed through a small number of designated airports—are implemented, local and state public health authorities need to be prepared to coordinate closely in order to identify monitored individuals crossing between jurisdictions and ensure the transfer of appropriate associated data (e.g., monitoring period, potential exposure/risk level). Depending on the particular HCID event, there may be federal programs in place to facilitate this coordination. If inter-jurisdictional coordination is beyond the capacity of the local response, assistance in this area can be requested from state and/or federal authorities.

Monitoring and tracking programs require significant resources and considerable personnel time and effort to implement, particularly at the local level. Face-to-face meetings, check-in phone calls, and database management—in addition to any ancillary health or social services—are time-, effort-, and resource-intensive activities, and personnel will likely be pulled away from their daily duties, at least to some extent. State and local public health entities need to ensure that they are capable of providing surge capacity to manage monitoring efforts. While public health authorities may not necessarily need to acquire equipment, pharmaceuticals, or other materiel that would normally be tracked by the Finance/Administration Branch, the Incident Commander should consider activating personnel to staff this branch in order to track and document personnel effort—for monitoring and other response programs—in order to justify reimbursement requests.

Monitored individuals may not always reside in the community at large. Local public health and healthcare systems need to establish relationships with local, state, and federal corrections systems (and similar facilities) in their jurisdiction and develop and exercise plans to identify, report, transport, and care for incarcerated individuals. Incarcerated populations pose unique challenges due to factors such as prolonged close contact with others, potential unwillingness or reluctance to seek care, limited on-site clinical and medical isolation capabilities, and requirements for patient escort (potentially including armed escort) [NOTE: This includes the challenges of accessing and using firearms and restraining the patient while wearing PPE and/or in a patient isolation setting]. Additionally, untrained personnel may be unwilling to interact with monitored individuals, especially if they develop symptoms. Corrections systems also need to conduct at least preliminary training with designated personnel regarding standard infection

control precautions and basic PPE and establish programs to conduct just-in-time training to familiarize required personnel with any enhanced PPE required for HCID events.

Local public health jurisdictions need to closely coordinate with healthcare facilities (and systems) regarding monitored individuals. These individuals may require care for conditions unrelated to the disease in question (e.g., pregnancy/childbirth, trauma, minor/major surgery), and healthcare facilities and personnel (potentially including EMS) need to be aware of the patient's monitoring status in order to ensure that personnel and other patients are properly protected while care is provided to the monitored individual. As discussed below (Section 5.5), depending on the individual's risk level and the associated confidence in this determination, some monitored individuals may be treated similarly to Persons Under Investigation (PUIs) or confirmed cases in order to ensure the safety of healthcare personnel and reduce the downstream impact on the healthcare facility or system.

4.4 **Decontamination**

Finding: *Environmental decontamination of exposed objects and buildings is hampered by a lack of scientific evidence, extraordinary expense, and a limited supply of willing or capable contractors.*

Guidelines on how to properly decontaminate areas and objects potentially contaminated with a HCID-associated pathogen may be unclear or uncertain. Public health agencies, in collaboration with other relevant agencies and private contractors, should seek sources of authoritative guidance for various pathogens in advance of an event and be alert to changing guidance during an event. Contractors should be identified in advance, recognizing however, that contractors may withdraw if public concern is too great. When possible, secondary contractors should be identified to replace or supplement the primary entity.

Similar to many other challenges discussed in this report, the desire to take actions that are intended to be comforting to the public, media, and others should not supersede the need for actions based on scientific evidence. Actions taken "out of an abundance of caution" undermine guidance and the scientific evidence and officials that support it. With many infectious diseases, all possible modes of transmission are not completely understood, but the distinction between theoretical and observed risk should be accounted for in preparedness and response efforts. The presence of some small amount of viral material on a surface or in a sample does not necessarily mean that material is infectious. These nuances are important but also difficult to communicate in a sound bite. Negative attention and concern over contamination, particularly for businesses, can pose significant challenges to their viability moving forward after the event. Public health and elected leadership should proactively make efforts to educate and reassure the public that all appropriate measures have been taken to protect their health and safety, but they should not be responsible for additional decontamination efforts that are not supported by science. Company owners or operators may take these actions on their own, if they feel they are necessary to reassure their clientele, but they should not be part of official response or recovery activities.

4.5 Waste Management

Finding: *Waste management, unexpectedly, may be one of the most challenging issues in HCID response.*

HCID patients can potentially generate enormous amounts of hazardous waste (both sewage and contaminated materiel), depending on the disease. Waste handling, transportation, and storage plans must be created prior to the onset of an event in order to facilitate the safe and rapid disposal of hazardous waste. Accumulated waste can have a significant negative effect on treatment facilities, particularly in cases where the waste must remain inside the "hot zone" with the patient and clinicians. In some cases, interstate transport of hazardous waste may be required, which may require coordination with the Environmental Protection Agency (EPA) and multiple agencies in multiple states. As was seen with the US domestic Ebola response, the public and media displayed considerable concern about the treatment of hospital wastewater and the potential for contamination. While hospital wastewater, contaminated with any number of pathogens, is properly treated on a continual basis during normal operations to ensure public safety, treatment facilities should be prepared to address these types of questions in the context of HCID-associated pathogens.

5 Healthcare-Specific Issues

5.1 Identifying Treatment & Assessment Hospitals

Finding: *Safely assessing and treating actual or potential HCID patients requires extensive preparation and training and can be a tremendous burden on hospitals and hospital systems.*

During the US domestic Ebola response, the CDC issued case definitions for both confirmed cases and Persons Under Investigation (PUIs). PUIs were defined as individuals with both non-zero epidemiological risk for Ebolavirus infection *and* symptomology consistent with EVD, whereas confirmed cases required laboratory diagnostic confirmation.[43,44] Due to their risk of infection, PUIs were often handled in the healthcare system in essentially the same manner as confirmed cases (e.g., patient placed in isolation, Ebolavirus infection control precautions/PPE implemented) while awaiting the results of confirmatory laboratory diagnostics. In December 2014, the CDC issued guidance recommending a three-tiered approach to designating hospitals' roles with regard to EVD patients: frontline facilities, Ebola assessment hospitals, and Ebola Treatment Centers.[45] In most cases, confirmed cases were treated at designated Ebola Treatment Centers; however, PUIs typically remained at the facility where they entered the healthcare system—although, in some places, they could be transferred to a designated assessment hospital for care while awaiting laboratory results.

Assessing, managing, and treating HCID patients requires, among other things, a skilled clinical team trained in proper PPE and a facility that can support proper isolation and care of the patient. In advance of an event, local and state elected and appointed officials and health sector leadership need to identify healthcare facilities (e.g., hospitals) that can be activated to serve as treatment

facilities for HCIDs. These facilities do not necessarily require developing and maintaining a dedicated biocontainment unit, but they need to have the capability to isolate patients for a range of diseases (including those that exhibit airborne transmission) and have highly trained and experienced personnel to provide clinical care and support.

Despite the designation of these specialized treatment centers, HCID patients will not necessarily enter the healthcare delivery system at one of these designated facilities. Every healthcare entity—including hospitals, public health clinics, and ambulatory care centers—should be prepared to identify and initially isolate a patient. Not every healthcare facility necessarily needs to be able to manage clinical treatment and long-term isolation, but minimal training and infrastructure need to be in place to safely handle HCID patients until they can be transferred to a better-equipped facility. Additionally, during the domestic response to cases of EVD in the United States, the CDC also issued guidance for Ebola assessment hospitals that could be designated in order to provide clinical care for PUIs while awaiting laboratory results. These facilities had levels of training and capabilities above those of front-line hospitals and other healthcare facilities but below those of the designated treatment centers.[46] These capabilities enabled them to safely provide some measure of care and longer term isolation without adversely affecting normal facility operations at front-line healthcare facilities or fully activating a treatment center.

The volume of PUIs and monitored individuals requiring medical care unrelated to the disease in question (e.g., childbirth, trauma injuries) may be considerably higher than the number of confirmed cases requiring specialized care. These patients may require additional resources compared to normal patients due to their elevated risk of infection, which could be particularly burdensome for front-line hospitals and healthcare centers. Local and state health sector leadership should consider developing a plan to triage PUIs and monitored individuals or designate facilities for the treatment and assessment of these individuals—which may or may not be the same facilities designated as treatment centers—in order to mitigate the impact on the broader health system. Depending on the disease and facility, a single patient could potentially have considerable impact on a facility, healthcare system, or entire city or region. For example, the use of specialized equipment (e.g., CT, MRI) for a HCID patient may render that equipment temporarily (or permanently) unavailable, which could negatively affect that facility's ability to conduct normal operations and/or result in increased demand on equipment at nearby facilities. Healthcare entities need to coordinate and plan with other facilities and healthcare systems prior to an event to ensure that any disruptions to clinical services are accounted for and addressed to mitigate the downstream impact of these types of patients.

In an ideal world, every healthcare facility would be fully equipped, staffed, and trained to treat HCID patients; however, the resources required to establish and maintain this capacity makes this prohibitive for all but a select few facilities. While establishing a designated treatment center is integral to improving the response to future HCID events, many interviewees voiced concern over maintaining these facilities during the interim periods between events. Maintenance of emergency preparedness funding is paramount to ensure that these facilities can remain operational. Additionally, maintaining the interest of those who have committed to being part of

the treatment team can be difficult and requires constant engagement. Many interviewees recommended continual activities such as drills and exercises to help maintain this interest. Lastly, a consistent, formal process to identify these facilities (e.g., determining who identifies and designates and certifies these facilities) is needed to ensure consistency across jurisdictions and facilities. Federal, state, and local public health and government officials; hospital administration, clinicians, and support staff; and representatives of other sectors across the healthcare delivery continuum must coordinate in advance of the next HCID event to standardize this process, identify resource requirements (e.g., number of facilities, minimum materiel stockpiles), and implement appropriate assessment and certification mechanisms.

US Centers for Disease Control and Prevention (CDC). Preparing for Ebola – A Tiered Approach. Available at https://www.cdc.gov/vhf/ebola/healthcare-us/preparing/index.html.

5.2 Hospitals

Finding: *Significant facility modifications are needed to safely accommodate a HCID patient.*

In addition to preemptively assembling a response team, healthcare facilities are encouraged to set up HCID treatment and isolation areas in ways that enable clinicians to effectively and safely provide care, regardless of whether the unit is converted from its normal daily function or a dedicated biocontainment suite. Considerations for the unit layout include:

- Patient transport into the isolation/treatment area
- Personnel traffic flow, including PPE donning and doffing and one-way traffic flow pattern
- Necessary equipment and supplies, including PPE storage, required laboratory capabilities, and substitutions for complex equipment (e.g., portable ultrasound in place of CT)
- Communication with healthcare personnel and the patient
- Patient bed capacity (may vary by disease)
- Waste storage and disposal (including autoclave throughput capacity)
- Ventilation, including negative pressure (e.g., patient room vs. unit/anteroom, unit vs. rest of the facility) and filtration
- Remote monitoring, including audio/video and patient vital signs
- Personnel standby/rest areas and locker room/showers

Facilities without dedicated or specially designed isolation/treatment units may not have ideal unit layouts for all of these, and they may have to make concessions in certain areas, with patient and healthcare personnel safety in mind. To assist with preparedness training and for response support, collaboration with experienced clinicians and hospital leadership through programs like NETEC can be very beneficial in identifying and anticipating challenges related to unit design, because each setup will be unique.

5.3 **Patient Identification & Triage**

Finding: *Rapid identification of potential HCID patients at the first point of contact in any healthcare setting is essential.*

Quickly identifying and triaging suspected HCID cases depends on astute clinicians—including those in ambulatory care settings, public health, and hospitals—who perform patient screenings and complete patient assessments and who are knowledgeable about the physical manifestations and epidemiology of the disease of interest. While not all healthcare facilities may be equipped to safely and effectively treat patients with the disease, all facilities must be capable of at least identifying, triaging, and isolating these patients. This includes knowing the appropriate questions to ask to determine if a patient is a suspected case, quickly placing the patient in an area removed from other patients, immediately implementing proper infection control measures (including PPE and proper room signage), notifying the appropriate health authorities, and arranging for diagnostic testing and patient transfer as appropriate. Because it may be difficult for clinicians to remain abreast of every infectious disease outbreak occurring across the globe, having an updated clinical resource that they can reference would be helpful in identifying worrisome travel histories. Additionally, utilizing electronic medical record systems that prompt users to complete a travel assessment and flag potential risks could reduce the chance that this information is overlooked or lost as the patient moves through the healthcare system.

During an infectious disease outbreak, there may be numerous individuals who are closely monitored by the public health department and who may, at some point, present to a hospital or ambulatory care center for unexpected and/or emergent healthcare needs unrelated to the disease in question, including trauma injuries, acute or chronic illness, and childbirth. Close coordination and communication between the public health department and local hospitals/ambulatory care centers can help facilities rapidly identify and isolate these individuals. Additionally, as noted by many interviewees, potential cases can present to any medical facility—particularly emergency departments—if in need of emergency care, and hospitals cannot refuse to evaluate and stabilize the patient based on the concern that they *may potentially* be infected. To prepare for such scenarios, hospitals need plans in place to provide safe and effective care in the context of uncertain disease status until the patient can be transferred to a designated treatment or assessment facility.

5.4 **Patient Isolation**

Finding: *Immediate isolation of potential HCID patients wherever they present is needed to protect other patients and healthcare workers.*

In most HCID events, patients will likely be placed in isolation to prevent transmission of the infection to others. Isolation facilities will inevitably vary between healthcare entities, ranging from converted rooms or wards normally used during daily operations to specially designed biocontainment suites with negative pressure and HEPA-filtered ventilation systems, anterooms, and advanced remote monitoring equipment that are only utilized for HCID patients. Regardless

of the setup and capabilities, all facilities across the healthcare delivery spectrum need the capability to separate HCID patients from others to prevent nosocomial infection. As discussed in Section 5.3, all healthcare facilities need to have basic training in isolation procedures and infection control to enable them to safely place a patient in isolation. The length of time that this will be required will vary based on the disease, patient condition and symptomology, and the status of the local or regional tiered hospital system, but all facilities need to be prepared to isolate a patient at least until they can be transported to a more capable facility.

While these patients must remain in isolation to protect against further spread of the disease, efforts should be taken to ensure that they are able to contact friends and family during their care. Phones, photos, and video chat (e.g., Skype, FaceTime) are some examples of mechanisms by which patients and their loved ones can remain in touch. Even low-tech solutions such as being able to communicate through a window can be beneficial. These same mechanisms can also allow the patient to access patient advocacy organizations and/or legal counsel, if necessary. These efforts not only benefit the patient, through knowing that they have support outside of the clinical staff, they can also provide comfort for the family and friends knowing that proper care is being provided for the patient. Additionally, if the patient wishes to communicate with the public (e.g., via traditional or social media)—and it is appropriate, considering their medical condition—this can reassure the public that the disease is being properly controlled and that proper care is being provided for the patient.

Similar to the quarantine measures discussed previously in Section 4.2, policies, regulations, and legislation for patient isolation must be developed and vetted in advance of a HCID event. While it is less likely that an ill patient will resist isolation than an asymptomatic individual will resist quarantine—particularly when it is a requisite for receiving clinical care—it is certainly possible, especially for events that cause significant fear in the community or diseases for which ill or recovered patients are stigmatized by the public or media. Healthcare facilities, public health, elected and appointed officials, and legal counsel must have plans in place to ensure that infectious patients remain in isolation in order to prevent spread of the disease in the healthcare facility and community.

5.5 **Limitations on Clinical Services**

Finding: *Infection control considerations may limit the availability of some clinical services for confirmed or potential HCID patients.*

Providing clinical care for a PUI or confirmed patient takes enormous resources, and healthcare facilities and localities need to consider that, for some HCIDs, patient volume may exceed their maximum capacity. Staffing levels, waste volume and disposal capacity, disease transmission route, and other factors may limit the number of patients a given facility may be able to treat. Additionally, healthcare facilities and personnel need to have an approach in place in advance of an event to determine the level of care that will be provided to a PUI or confirmed case. The moral obligation to provide life-saving treatment (e.g., hemodialysis, surgery, CT scans, CPR) to a

critically ill patient is compelling; however, in some cases, certain procedures may pose risks to healthcare personnel and/or other patients, or specific equipment or procedures (e.g., surgery) may not be available due to patient transport or contamination concerns. Permitting the use of certain specialized equipment (e.g., CT scanner, MRI machine, laboratory instrument) for a PUI or confirmed HCID patient could potentially render that equipment unusable for other patients due to contamination concerns. Issues with equipment availability could also have considerable negative downstream effects on citywide or regional health systems, as other facilities must be identified to provide these services. Interview participants indicated that hospitals were forced to weigh the potential risk to their personnel and consider the potential downstream impact on their health system operations in making this determination, acknowledging that it could potentially limit the scope of healthcare services available to the individual.

Because PUIs have not been conclusively diagnosed with a HCID, it can be exceptionally difficult to place limitations on how they will be medically treated, given the possibility that they may not be infected at all. The variables for each individual will depend on the pathogen, the patient's medical condition, and their status as a PUI or confirmed case. Interviewees suggested implementing a crisis standards of care approach[47] and stressed the importance of a risk-benefit analysis to determine what clinical procedures should and should not be undertaken. Assembling a multidisciplinary team of clinicians, ethicists, infection control practitioners, industrial hygienists, and others can help facilitate discussions and guide decision making. Additionally, expectations need to be laid out very clearly to the patients (both confirmed and PUI) and their families to emphasize the commitment to both the patient's wellbeing and the safety of the staff and other patients.

In anticipation that a PUI or confirmed patient will need to be transferred to another area of the hospital for special procedures (e.g., MRI or CT scan, surgery, childbirth), treatment facilities need to establish protocols for how the patient will be transferred, including who will be involved and what route will be taken. [NOTE: In many cases, the clinical treatment of confirmed cases may be limited to the isolation area, so patient transport may be of greater concern for PUIs.] These plans should also include identifying transport, surgical, anesthesia, and other personnel who may be involved and conducting training on proper PPE donning and doffing requirements and other infection control practices.[48] Additionally, protocols on the proper decontamination of specialized areas outside the isolation area (e.g., operating room/suite) should be developed in close coordination with environmental cleaning and infection control leadership and staff to help ensure their prompt return to operational status as well as the safety of hospital personnel.

In addition to formally identified PUIs, other monitored individuals could potentially pose problems for healthcare systems. While not technically a PUI under the official CDC definition, one could easily imagine a scenario in which an individual with non-zero risk of infection presents to an emergency department or clinic for an unrelated condition (e.g., childbirth, trauma, minor surgery), during which they may be treated as a PUI until the completion of confirmatory laboratory diagnostics. As discussed previously, some infectious disease responses may include monitoring programs for individuals at risk for developing the disease in question

(i.e., individuals with non-zero risk but currently displaying no symptoms), and it is likely that these individuals may be treated as PUIs upon entering the healthcare delivery system, particularly if the individual is in a higher risk classification or there is uncertainty about potential exposures.

5.6 **Research**

Finding: *Treatment of HCID patients likely involves research-related issues, particularly with respect to clinical care protocols and investigational pharmaceutical products.*

Caring for patients with HCIDs such as EVD opens the door for numerous research projects that can help inform the management of future outbreaks and the treatment of those infected. Healthcare facilities should develop rapid institutional review board (IRB) approval processes, in close consultation with their IRB and ethics committees, to ensure that these potential opportunities are not lost waiting for proper approval. By planning in advance of an event, a streamlined process can be established to facilitate obtaining informed consent from the patient, requesting and receiving the investigational products from the manufacturer, and coordinating with the Food and Drug Administration (FDA) to obtain necessary emergency authorizations. While streamlined to reduce the time required, this process must ensure that all proper oversight remains in place—in particular, the process of obtaining informed consent from the patient. Additionally, these research endeavors should be coordinated and led by an expert in clinical research to ensure adherence to the highest scientific standards and to relieve the clinical team of additional tasks not directly related to patient care (e.g., identifying and collecting appropriate data).

Clinical staff responsible for treating the patient may not be trained in conducting clinical research, including obtaining informed consent, and may not be experienced in administering the specific investigational product being used. Training conducted in advance of an event can familiarize clinicians with research protocols and informed consent requirements, and just-in-time training will be vital to ensuring that the investigational product is administered properly and that required data is collected systematically. Interview participants recommended adding one or more clinical research nurses to the treatment team, which could help improve communication and coordination between clinical and research personnel.

It is important to note that research is not limited to pharmaceuticals, and many other research opportunities exist during the management and care of HCID patients that can help advance the holistic management of future patients as well as the science of the pathogen itself. Performing quality observational research—such as documenting hemodynamics, ventilation requirements, nutrition, and even PPE use or infection control measures—can provide the data needed to help researchers and clinicians identify best practices to improve future efforts. One of the major challenges of conducting clinical trials in HCID patients in advanced clinical settings is the lack of baseline data for control subjects. The standard of care provided in US hospitals differs wildly from what patients can receive in developing countries, and the systematic collection of data for

HCID patients in the United States could be vital for assessing the effect of existing and future investigational products. Additional research areas include mental and behavioral health for HCID patients and modes of infection transmission to advance the epidemiologic understanding of the pathogen, both of which could help manage and/or prevent future HCID events.

5.7 Equipment Decontamination

Finding: *Potential or actual contamination of medical equipment may limit their availability to both HCID and other patients.*

During the 2014 Ebola response in the United States, multiple laboratories that performed diagnostic and other tests for confirmed EVD patients were informed that equipment manufacturers or service companies would no longer perform maintenance or certification on some of their equipment because it had been contaminated with Ebolavirus. Because of these issues, several extremely expensive pieces of equipment had to be destroyed and replaced. Similarly, some clinicians indicated that equipment used for the care or diagnosis of a HCID patient could potentially be rendered unavailable for other patients, either temporarily or permanently, due to contamination concerns. Interviewees warned that facilities should be aware that normal decontamination procedures may be insufficient to satisfy equipment manufacturers or maintenance companies and that additional efforts may be needed to ensure that equipment can continue to be used for future patients. Health system leadership should engage with equipment manufactures and maintenance companies or technicians in order to anticipate these types of problems. Additionally, health systems should have a system in place in advance of a HCID event that outlines how to decontaminate high-value equipment, particularly because many healthcare facilities do not have the resources to replace expensive equipment. Additional research in this area would be useful to help inform these guidelines. Finally, healthcare facilities should identify alternatives to high-value equipment in order to perform similar functions without the risk of losing valuable equipment. For example, portable ultrasound units can potentially serve as a suitable substitute for MRI or CT scans.

6 Healthcare and Public Health Workforce Issues

6.1 Psychosocial Effects

Finding: *Providing care to HCID patients places extraordinary stress on healthcare workers.*

Taking care of critically ill patients is inherently mentally and physically exhausting for healthcare workers, but caring for EVD patients exposed new vulnerabilities beyond those experienced during normal, everyday duties. Interviewees revealed that the long hours under stressful conditions, the inability to share one's experience outside of the treatment unit, and challenging patient care—including the often-poor prognosis—was particularly taxing on clinical and support personnel. Additionally, healthcare workers were often required to undergo monitoring themselves due to their risk of exposure, which further isolated them from their family and friends as well as the coworkers that they work with on a normal, daily basis (e.g., their normal

"home unit"). Fear that they might infect their loved ones and stigmatization from coworkers, family, friends, and the public further compounded their stress.

Many respondents recommended providing emotional and mental health support to treatment staff during future HCID events—either from chaplains, counselors, hospital leadership, or other appropriately trained individuals—to help them cope with the additional stress. Performing "wellness screenings" before and after each shift could help identify those who are struggling, because healthcare workers may be predisposed to underreport mental health issues and disregard personal issues in order to continue treating the patient.[49,50] Strong, trusted relationships between clinical team personnel and leadership and sharing their experience with healthcare workers at other biocontainment units or treatment facilities may help boost morale and foster honest and open exchange with one another. As stated by clinicians who took care of EVD patients during the outbreak, sharing experiences with one another served as a relief valve for stress and helped identify those who were experiencing additional stress. Because many personnel may experience apprehension, anxiety, or fear about providing care for a HCID patient, having open communication with hospital leadership and continual PPE training can build confidence and trust in the system. Additionally, involving the team in developing and evaluating products (e.g., PPE) and protocols helps establish their buy-in, makes them feel like their opinions are valued, and builds confidence in the protocols they help to develop. Lastly, many of the clinical staff taking care of EVD patients felt like their absence was burdening their "home units" and noted that having the reassurance and support from co-workers that their normal duties are being managed can help alleviate some of the additional stress.

Additionally, because treating HCID patients can result in concern, anxiety, or fear in other patients and healthcare personnel, facilities need to actively reach out to patients and staff to educate and reassure them that every effort has been made to ensure their safety. Facility leadership should be transparent about the known facts, including safety precautions taken, and provide support to other patients and staff. Lastly, hospital plans should ensure that those involved in the response are properly taken care of, including providing meals and accommodations, recoupment of lost wages during monitoring periods (if applicable), support for family/children, and emotional/mental health services.

6.2 **Staffing Levels & Availability**

Finding: *Providing care to HCID patients requires extraordinary numbers of personnel from many different departments.*

Depending on the disease in question, staffing a treatment team during a HCID event may require more personnel than anticipated. For example, the treatment of EVD patients required additional personnel specifically trained to observe PPE donning and doffing procedures, and the type of PPE used precluded long stay times in the patient area for clinicians. Additionally, as noted in Section 6.1, staffing these specialized treatment teams took personnel away from their normal daily duties. Treatment and assessment facilities must plan for providing surge staffing to

supplement personnel removed from their "home units" in addition to the personnel required for the HCID treatment team. Since treatment personnel may be required to undergo a monitoring period afterward that could potentially keep them from returning to their daily duties for days or weeks, hospitals should expect that supplemental staff will be needed well after patient care has ended.

Limiting the number of individuals going into and out of patient care rooms is important, as minimizing unnecessary personnel helps decrease the probability that the pathogen will be transmitted to other individuals. Patient isolation rooms tend to be small, so limiting personnel in the patient area is important to enable clinicians enough space to effectively perform their duties. Furthermore, additional time and personnel are required to facilitate the PPE donning and doffing processes, so limiting personnel in the "hot zone" can also reduce the need for support staff. Teams with skilled personnel who are capable of performing a wide range of procedures or duties are extremely valuable on a treatment team in order to reduce the number of people in treatment areas. For example, nurses who could draw their own blood samples eliminated the need for a phlebotomist to enter the high-containment patient isolation area. Conversely, having an additional person in the room to perform specific tasks may pose less risk than assigning someone tasks that they are unable to perform safely or effectively. As with all aspects of HCID events, risk-benefit analysis is critical to determining personnel requirements.

6.3 **Voluntary *vs* Mandatory Staffing**

Finding: *Whether healthcare workers volunteer to take care of HCID patients or are mandated to do so may vary based on institutional culture, the type of personnel, and the number of HCID patients.*

Each of the locations interviewed used different methods to identify staff—including clinicians (e.g., MDs, RNs, respiratory therapists) and non-clinicians (e.g., waste management, environmental cleaning)—that would be involved in the management and treatment of HCID patients. According to most respondents, in an ideal world, all staff would volunteer to be a part of the treatment team and would view attending training, exercises, and drills as vital to their success and safety. This was the case for programs with well-established and dedicated biocontainment units more so than other facilities. Some of the considerations for programs with voluntary participation included: allowing those with families to self-select not to participate and the belief that participants would be more invested in training and patient care if their participation were not mandatory.

Depending on the staffing level, number of patients, experience, and staff willingness as well as patient condition and disease, facilities may be forced to mandate participation in patient care. Primary considerations for programs with mandatory participation included:

- Concern that not enough personnel would volunteer
- Concern that personnel would volunteer for training but quit when a patient arrived
- Not wanting to set a precedent that personnel could opt out of treating certain patients

- Concern that providing this option would be somehow acknowledging that these personnel were actually at an increased risk of infection, despite the infection control measures in place

Voluntary participation may also vary by type of personnel (e.g., doctor, nurse, infection control, other specialists), but this policy could be controversial as it may be viewed as unfair that some staff are permitted to choose while others are not. As noted by most participants, the issue of mandatory *vs* voluntary staffing is a very complex issue, and there is no universally effective approach. This decision will likely be dependent on facility size, staff availability, unionization of staff, and type of staff (e.g., RN, MD, environmental cleaning) as well as the disease itself. Interviewees recommended involving an ethics committee to help sort through these issues to decide what protocols work best for each facility.

6.4 **Clinical Training, Education, & Drills**

Finding: *The training demands needed to achieve and maintain proficiency in HCID care are considerable.*

Regardless of whether treatment team staff will be mandatory or voluntary, it is paramount that they are educated, trained, and drilled prior to taking care of a HCID patient to ensure their safety and to promote smooth operations. This can be complicated because, for many HCID-associated pathogens (particularly emerging and re-emerging), there exists little firsthand experience among clinicians nationwide on how to safely manage and treat these patients. Therefore, it is important to have timely, accurate information and treatment/patient management protocols (including PPE) from a single centralized source (e.g., CDC) to provide initial clinical guidance. Additionally, training and education does not stop once treatment of a HCID patient begins. As guidance changes, healthcare workers must adapt their protocols and procedures—particularly for PPE—to ensure their safety and proficiency. Just-in-time training may also be required to bolster the treatment team during patient care or to add critical skills not already on the team. Educating other personnel who are not part of the treatment team can provide reassurance that their coworkers are not endangering them, reduce stigma against those personnel on the treatment team, and calm the anxieties of other patients within the hospital.

Even during the interim periods between HCID events, frequent training and exercises are necessary for maintaining proficiency in protocols, especially for PPE donning and doffing procedures. These training opportunities also help keep personnel engaged in the time between HCID patients and provide a mechanism to evaluate and update protocols as necessary. Training and exercises should not be limited to the treatment team; integrating external partners such as EMS, law enforcement, and public health can help foster stronger relationships and develop a more cohesive response capability. No-notice and "mystery patient" drills can be a valuable training tool. These exercises involve actors presenting to emergency rooms and other healthcare facilities without informing personnel beforehand in order to improve screening and isolation

capabilities across the spectrum of the healthcare delivery system, improving the ability to recognize HCIDs at a variety of healthcare facilities.

6.5 **Clinical PPE**

Finding: *Meticulous attention to the proper use of appropriate PPE is necessary to protect personnel.*

Providing staff with up-to-date PPE guidance—including specific products and donning/doffing procedures—that is based on scientific evidence is vital to ensuring their safety while providing care for highly infectious patients and preventing disease transmission to other patients. Clinicians and healthcare leadership should be aware that PPE guidance may change as additional information is collected over the course of an event response—particularly for events involving diseases for which there is little firsthand clinical experience—and be prepared to adjust protocols as necessary to ensure their safety. Often times, initial PPE guidance is based on firsthand experience with the disease; however, this experience may be in vastly different conditions than what can be expected in the US healthcare system. Respondents emphasized that, in the absence of clear guidelines, consulting with peers who have worked with the disease outside of US borders—such as those who treated EVD patients in West Africa—can be extremely insightful. Adapting PPE protocols for advanced healthcare settings, however, can pose unique challenges (e.g., additional layers of protective clothing can be problematic for doffing procedures).

Healthcare personnel require fairly extensive training on PPE use and donning/doffing procedures to develop full proficiency. Infectious disease outbreaks often occur without warning, however, so just-in-time training may be all the training that some personnel receive. Under these circumstances, newly trained individuals cannot necessarily be expected to perform donning/doffing procedures perfectly by themselves. Additionally, complex PPE protocols (e.g., hoods, multiple layers of gloves) may make it extremely difficult for an individual to safely complete donning/doffing procedures on their own, regardless of their level of proficiency. Interview participants recommended that some PPE donning and doffing procedures be observed by a partner/buddy in order to ensure proper completion of these procedures. These observed procedures can help ensure that personnel perform each step correctly and do not miss any steps. Depending on the level of contamination of the PPE, it may also be beneficial for the observer to actively assist personnel during the doffing procedure in order to prevent the individual from accidently contaminating themselves. [NOTE: This will likely require that the observer wear enhanced PPE as well to ensure their own safety.] Regardless of the level of training an individual has received, it is highly recommended that they undergo a validation assessment by a trained observer to ensure that they are capable of completing donning and doffing procedures safely before they are permitted to access any part of the "hot zone."

In some cases, specially designated treatment teams may deviate from official PPE guidelines, because they have extensive training and experience with a different—but equally effective—PPE protocol. It may be safer for these teams to continue utilizing PPE with which the personnel are

already intimately familiar and more comfortable. During the US Ebola response, long-standing teams with years of training implemented PPE protocols that differed from CDC guidance (and each other), because their personnel had significant experience donning, doffing, and working in that PPE. Even though the PPE protocols do not necessarily align, personnel can reduce the likelihood of mistakes during donning/doffing procedures by using something they are familiar with.

7 Laboratories

Finding: *Both routine and disease-specific laboratory diagnostics may be limited during a HCID event.*

During the US domestic Ebola response, clinicians faced a variety of laboratory issues during the testing and treatment of PUIs and laboratory-confirmed patients, due in large part to the poor availability of confirmatory diagnostics in the United States. The vast majority of diagnostic laboratories did not have readily available diagnostic tests or reagents for Ebolavirus infection, and for a period of time, all samples were required to be shipped to the CDC in Atlanta, Georgia for confirmatory testing. In addition to the challenges of identifying laboratories with the capability to perform these tests, healthcare facilities struggled to determine appropriate packaging and shipping requirements for the associated specimens. Furthermore, many shipping companies and couriers refused to transport samples being tested for Ebolavirus infection, severely limiting the options available to those needing to ship clinical specimens. The requirements for packaging and shipping these samples, in combination with the perceived risk of infection resulted in exorbitant costs for shipping each specimen.

The regulations governing these shipments, including the Select Agent Rule (§42 CFR part 73), were confusing to some of the local laboratories. Several interview participants indicated that they had significant problems storing and shipping specimens from confirmed cases after patient care ended. Because these samples contained Ebolavirus, they became regulated under the Select Agent Rule once live virus had been isolated. Facilities that retain some specimens but are not authorized to possess Select Agent material may be forced to destroy valuable specimens if they cannot be transferred to an authorized laboratory. Close coordination with federal authorities is required to determine what types of samples are regulated under these rules, how to proceed appropriately, and how to facilitate proper storage, shipping, and use of these specimens.

Identifying laboratories, particularly those in the local area, that can perform the necessary diagnostic tests in advance of an event could significantly mitigate the challenges of completing diagnostic tests and reduce delays during the response. HCID events, however, do not always come with advance warning, and they may involve pathogens for which there are not widely available diagnostic tests. Under these circumstances, healthcare systems need to have established packaging and transfer protocols in place to safely and efficiently ship samples to laboratories with the appropriate diagnostic capabilities.

Local and state health officials can help healthcare systems identify and contract couriers who are willing to transport specimens potentially infected with HCID-associated pathogens and who maintain the proper licensing to do so. This should be done in advance of an event in order to reduce delays in completing diagnostic tests. It is also recommended that secondary options be identified, when possible, in order to provide redundant shipping capability in the event that the primary contractor backs out or is otherwise unable to perform these services. It is also notable that, even for those facilities that can locally test for highly infectious diseases, samples may still need to be sent to the CDC for confirmatory testing, so they must plan accordingly.

Lastly, HCIDs may initially manifest with symptoms similar to a number of more common diseases. It is recommended to perform laboratory diagnostics for more likely diagnoses (e.g., malaria, dengue) that can be tested for more quickly in on-site laboratories. Laboratory diagnosis of these diseases will not necessarily rule out a HCID, but delaying additional laboratory testing while awaiting the results of HCID tests only further delays patient care. As discussed in Section 5.7, however, additional consideration must be given to the impact of potentially contaminating laboratory equipment with HCID-associated pathogens during these routine tests.

7.1 Quality Assurance & Proficiency

Finding: *Establishing and maintaining readily available laboratory capacity for HCID patient care is a challenge.*

In addition to diagnostic capabilities, routine laboratory tests such as complete blood count (CBC), basic metabolic panel (BMP), and blood gas assays are vital to patient care. Some biocontainment units and specialized treatment centers have the necessary laboratory equipment available either inside the "hot zone" or nearby (e.g., in the biocontainment suite), while others rely on laboratories outside the isolation area. Both systems have their own relative benefits and limitations. Either setup can be implemented effectively, but a risk-benefit analysis should be employed to determine the best option for each individual facility.

For equipment inside the isolation or patient area, routine preventive maintenance, regular calibration, and quality assurance procedures become challenging. Unlike equipment in normal laboratories, this equipment may not be used on a regular basis, and dedicated efforts are needed to ensure they are routinely calibrated and certified. Additional challenges for this setup include training and ensuring proficiency for those using the equipment. It may be possible to train clinical personnel to perform certain procedures in order to reduce the need for laboratorians in the "hot zone" or patient area. In some cases, however, it may be better to utilize fully trained laboratory personnel to perform these tests, but additional training will be needed to ensure that they are also proficient in the use of required PPE and other safety protocols. For facilities that consider adding laboratory capacity to their isolation unit, it may be preferable to have laboratory capacity nearby but not necessarily in the patient area in order to reduce the number of personnel required to be in the "hot zone." In addition to laboratory equipment, calibration of other equipment—including autoclaves—must be considered as well.

For those units that utilize a laboratory outside the isolation or patient area, the packaging and transport of specimens from the isolation area to the laboratory can be a challenge, as this inherently involves the pathogen being removed from the isolation/containment area. Additionally, while this setup reduces the amount of additional training required (e.g., laboratorians on PPE, clinicians on test procedures), utilizing laboratory equipment for HCID-associated pathogens could pose problems for decontamination and availability (as discussed in Section 5.7). Finally, utilizing fully operational laboratories potentially enables clinicians to access a wider range of tests than what may be available inside a containment area.

7.2 Laboratory PPE & Training

Finding: *While some clinical laboratorians have appropriate biosafety training and experience to work in a high-containment environment, most do not, which further limits the availability of laboratory testing for HCID patients.*

While clinical PPE requirements may evolve as more clinical data becomes available—as was seen during the US Ebola response—the same may not necessarily be true for laboratory personnel that operate in high-containment (e.g., Tier 1) laboratories. Laboratory personnel are often already trained on appropriate biosafety and laboratory safety procedures for their laboratory, including PPE, as well as the equipment required to process samples for HCID-associated pathogens and conduct the required diagnostic tests. One interviewee cautioned, however, that this could be a dangerous assumption, as there is variability in the training of laboratory technicians, particularly dependent on the type of laboratory. Lower tier laboratories may not have the same level of proficiency with respect to biosafety measures as higher containment laboratories. Additionally, the perceived risk of handling high-consequence pathogens could deter some technicians from working with these samples. Ensuring that laboratory technicians have the proper safety and PPE training and the necessary skills to perform appropriate diagnostic tests and are knowledgeable about the risks of the disease is paramount to conducting safe and efficient laboratory operations.

8 EMS and Patient Transport

Finding: *Extraordinary planning, precautions, and coordination are required to transport confirmed or potential HCID patients*.

Transfer of a confirmed EVD case or PUI from one location (e.g., hospital, detention center, airport, home) to a designated assessment or treatment center during the US Ebola response was often fraught with unforeseen challenges not experienced during the normal, everyday patient transport. Examples included PPE and patient hand-off protocols, decontamination and removal of waste from the transport vehicle, and intense media and public scrutiny. Each patient will likely pose unique challenges based on their medical condition, location, risk level, and receiving facility, but proper advance planning can mitigate many of these issues.

One of the biggest factors in mitigating these challenges is multi-sectoral communication and coordination. Coordination between public health, healthcare, EMS, and law enforcement can help identify PUIs before the point at which they actually enter the healthcare system. This can be accomplished through a variety of mechanisms, including public health monitoring programs and by screening 9-1-1 calls for specific symptoms associated with the disease of interest—particularly when paired with travel history or other exposure information. Information identified through these channels can provide advanced notice for EMS and other healthcare personnel that can enable them to take proper infection control precautions prior to interacting with the patient. These notices can also be used to place specialized patient transport teams on alert status in order to decrease response time in the event that they are needed. Monitored individuals should be instructed to contact the health department in the event that they become symptomatic or require care for an unrelated condition, and public health officials can pass this information on to the appropriate receiving facility or EMS dispatch to notify them of the individual's PUI status.

The constant media presence and public interest in the transfer and treatment of confirmed EVD patients or PUIs often hampered the ability to safely and quickly transport them to designated facilities. Because radio communications for response personnel could potentially be monitored by the media or public, some interviewees recommended implementing code words as a covert means of notifying response personnel of PUIs or monitored individuals without alerting the media or public. Additionally, these covert communication methods could increase patient privacy and security during patient transport. Another option for PUIs, depending on the patient's medical condition, was to encourage the individual to utilize their own vehicle and transport themselves to the hospital. This would reduce the need for unnecessarily standing up specialized transport teams and expending resources for decontamination. Because the PUI would be arriving at the facility on their own, close coordination would be required with the receiving facility to ensure that the individual was identified and isolated immediately upon arrival.

The patient transport efforts and recommendations outlined above helped to ease the challenges of transporting EVD patients during the event, but many respondents noted the need to form transportation networks and transfer protocols prior to a HCID event in order to streamline the process and improve coordination among involved agencies. For example, creating a designated patient transport network that includes representatives from public health, healthcare, EMS, law enforcement, and other emergency responders that regularly train and drill together can help build familiarity with patient transport procedures and response protocols across the relevant sectors. Training and exercises should address a range of transport scenarios, including various starting locations (including air/seaports and other healthcare facilities), known and unknown patients, and secondary/backup assessment or treatment facilities. This coordination could prove especially important in scenarios that involve multiple different jurisdictions and associated state or local laws.

In locations where they exist, well-trained CBRNE or hazardous material tactical (HAZTAC) units can be a valuable resource for patient transportation, as these units have specialized training in

advanced PPE and are typically integrated into law enforcement, firefighting, and EMS networks. These personnel are already experts in safely donning and doffing PPE and likely have at least some basic medical training that would allow them to serve as specialized patient transport teams. On the other hand, a HAZMAT response is expensive and involves a multitude of vehicles and individuals which could impede traffic flow around the hospital—particularly in large, metropolitan centers—and potentially amplify fear amongst the public.

Patient transfer and hand-off protocols should also be developed in close coordination with applicable agencies (e.g., healthcare facilities, EMS, law enforcement, public health) prior to an infectious disease event. These protocols should include specific instructions for collecting and sharing patient data and checklists for required actions for all applicable agencies, and regular exercises (both tabletop and full-scale) should be conducted to identify gaps prior to an event. To simplify the process, one EMS department developed a portable checklist that included useful information such as the facility layout for the destination hospital, patient transfer location, overhang clearance heights, and action checklists for both EMS and hospital staff as well as basic patient information in order to avoid delays during patient transfers. EMS decontamination and waste management protocols should also be adopted prior to an event to ensure proper disposal of all patient waste from the transport vehicle and to address decontamination logistics for the vehicle, equipment, and personnel—including where it will occur and who will perform it—so that the unit can return to operational status.

In addition to the need for transport networks and transfer protocols to ensure a safe patient transfer, planning must also include establishing and maintaining a stockpile of appropriate materiel (e.g., PPE, decontamination/sanitation products) that can rapidly be made available to support patient transfer activities. Entities that are likely to be involved in the transfer of patients (e.g., state and local public health, hospitals, EMS, police department) should coordinate with one another to identify who will procure and maintain the stockpile. The stockpile does not necessarily need to be controlled by a single entity, but coordination is required to ensure that materiel requirements are met for all involved entities and that resources are distributed appropriately.

RECOMMENDATIONS

The intended audience for this checklist is the set of individuals and organizations who have some responsibly for preparing for and responding to a high-consequence infectious disease (HCID) event at the state or local level. There are important issues, however, that cannot be addressed at the state and local level, and we acknowledge these and call for national action to address them. Included in this category are:

1. A need for sustained national preparedness including substantial and sustained federal funding
2. Sustained funding for the basic public health infrastructure necessary for disease detection, surveillance, and response
3. Clear, unified federal guidance for public health and healthcare practitioners
4. Clear identification of federal leadership during HCID events
5. Real-time research to identify, evaluate, and produce effective countermeasures and treatments

General Checklist

The following is a checklist of overarching actions that many different health sector organizations can implement to foster resilience.[iii] Following this general checklist, we provide supplemental checklists that are specific to individual components of the health sector. Some of these items may be very challenging to accomplish and may require considerable effort over time and collaboration across multiple government and community partners.

Preparedness

- The organization has the trained personnel needed to prepare for and respond to a major outbreak.
- The organization partners with other organizations that may be involved in a response, such as through a Healthcare Coalition (HCC). Such partnerships provide a mechanism for information sharing, collaborative exercising and training, planning, and surge response.
- The organization has an all-hazards emergency response plan with annexes for infectious diseases and routinely exercises components of the plan with partners.
- The organization has incorporated lessons learned from the 2014 domestic Ebola response into ongoing organizational and community HCID planning.

[iii] Some items in this checklist may overlap to some extent and are not intended to be mutually exclusive.

Leadership

- The organization is prepared to identify a single leader early in the response.

Creative Flexibility

- The organization is prepared to adapt existing plans in the midst of a response in order to address the specific needs of the particular incident and adjust response activities as knowledge, facts, and resulting guidance evolve during the incident.
- The organization has practiced (through exercises) adjusting operational procedures during an outbreak in the context of new knowledge, uncertain science, and/or differences in professional opinions.

Command Structure

- The organization is prepared to use the familiar Incident Command System (ICS) chain of command/command structure that is used for other events/responses.
- Incident Commanders have ready access to information on the roles and authorities of the federal, state, and local agencies during infectious disease emergencies.
- Incident Commanders are familiar with the larger incident command structure of the jurisdiction/state.

Public Trust

- The organization routinely engages community stakeholders—including community and faith-based organizations (CFBOs) and local opinion leaders—to identify and address community health needs, thus building public trust in advance of an event and developing partnerships that can prove valuable in a crisis.
- The organization is reaching out to the media, public, and elected officials in advance of an event to educate them about HCID preparedness and response activities and policies.
- The organization has a strong risk communication capability and is prepared to mount a robust media and community outreach campaign during an event as part of a coordinated effort between the healthcare delivery system and state and local public health.

Managing Uncertainty

- The organization has established a decision-making process that incorporates the most current and authoritative information available, including a process for adjudicating conflicting information.

- The organization is committed to taking actions that are supported by scientific evidence and avoiding, wherever possible, actions that are taken "out of an abundance of caution."
- The organization is committed to being honest and transparent with the public in cases where there are genuine differences of professional opinion in the context of uncertain science.

Crisis & Emergency Risk Communication

- The organization has trained risk communicators to craft and deliver clear, consistent, honest, and transparent messages to the public (including the media) and response and non-response personnel. These individuals should have a solid background in communication science, and communication efforts should be coordinated between healthcare and local/state public health entities.
- The organization is prepared to use multiple communication approaches, including town-hall meetings, websites, social media, guest spokespersons, and information call lines/centers to get information out to the public quickly and to provide the opportunity for the public and media to ask questions and voice concerns.
- The organization is prepared to monitor social media to rapidly identify and dispel rumors and correct misinformation.

Public Health Checklist

- As with any infectious disease event response, the agency must have appropriate and effective plans in place to address disease surveillance and detection; notify relevant state and federal authorities, local healthcare systems, and the public; and respond to a range of infectious disease threats. These plans must be exercised and assessed regularly and updated as necessary.
- The agency has a well-established communication network capable of providing vital information to state and federal authorities and the local healthcare system as well as conducting education and risk communication efforts for the media and public.
- The agency has well-established collaborative relationships with partner organizations such as healthcare facilities and other public health agencies (e.g., emergency medical services [EMS], state public health department, neighboring health departments, law enforcement).
- The agency has a clear understanding of its relevant public health and safety responsibilities and authorities as well as those of other organizations with which they might interact.

- The agency—in close consultation with legal experts—has ensured that officials understand the scope and limitations of public health laws and policies and identified who has the authority to enforce them.

- The agency has clear and practical policies on isolation of infected individuals that are soundly based on scientific evidence. These policies should minimize infringement on individuals' civil rights to the extent possible while still remaining effective as an intervention. These policies should address the clinical care of infected individuals as well as factors such as legal counsel and due process (including expeditious processes to challenge mandatory isolation), patient privacy, mental health support, and communication with family and friends.

- The agency has clear and practical policies regarding quarantine of exposed individuals that are soundly based on scientific evidence. These policies should minimize infringement on individuals' civil rights to the extent possible while still remaining effective as a public health intervention. These policies address issues such as legal counsel and due process (including expeditious processes to challenge mandatory quarantine); clinical care for unrelated medical conditions; patient privacy; food, drink, and clothing (including personal and religious restrictions); mental health support; adequate shelter (particularly for homeless individuals); recuperation of lost wages; care for family members and pets; and communication with family and friends.

- The agency has coordinated with local law enforcement to ensure that, if necessary, law enforcement officials are able to provide security at the isolation/quarantine location to provide protection for the affected individual and ensure that the individual complies with mandatory isolation/quarantine orders.

- The agency is aware of resources available to provide public health law expertise.
    - The Network for Public Health Law: https://www.networkforphl.org/

- The agency has a process for implementing clear, consistent, and practical guidelines for monitoring programs, as appropriate, that are based on the level of exposure risk. When monitoring and tracking are necessitated, some form of personal interaction can be beneficial; electronic tools (e.g., telephones or internet) can facilitate monitoring programs by reducing the burden on both the monitored individual and public health personnel.

- The agency has identified personnel who will be in charge of monitoring and tracking individuals in advance of an event in their jurisdiction. State and local public health entities need to ensure that they are capable of providing surge capacity to manage monitoring efforts, including tracking personnel time and effort for potential reimbursement.

- The agency is aware of the needs of special populations—including children, the elderly, people with impaired cognition or mobility, non-English speakers, incarcerated populations, and homeless individuals—when monitoring and tracking programs are required.
- The agency has plans to monitor individuals in the corrections system and has coordinated with corrections facilities to identify, report, transport, and care for incarcerated individuals under monitoring or investigation. Additional planning may be required to ensure compliance with requirements for law enforcement escort, potentially including armed escort.
- The agency has a process for determining who requires investigation for possible infection based on symptoms and exposure. To the extent possible, this definition should be consistent with federal guidelines.
- The agency has coordinated with healthcare facilities regarding monitored individuals who are at some risk for infection. Monitored individuals may require care for conditions unrelated to the HCID in question (e.g., pregnancy/childbirth, trauma, minor/major surgery), and healthcare facilities and personnel, including EMS, need to be aware of patients monitoring status in order to ensure that healthcare personnel and other patients are properly protected while care is provided to monitored individuals.
- The agency, in collaboration with other relevant agencies and private contractors, should seek sources of authoritative guidance for decontamination and waste handling requirements for various pathogens in advance of an event and be alert to changing guidance during an event. Contractors should be identified in advance, recognizing, however, that contractors may withdraw if public concern is too great or be otherwise unable to perform necessary services.
- The agency is aware that interstate transport of hazardous waste may be needed, which may require coordination with the Environmental Protection Agency (EPA) and multiple agencies in multiple states. Coordination with relevant federal agencies as well as those in neighboring states in advance of an event can help mitigate issues associated with interstate hazardous materials transportation.

Healthcare Checklist

- The organization, like all healthcare facilities, is capable of screening for symptoms and medical and travel history that would indicate possible exposure or infection.
- The organization, regardless of the facility type (e.g., clinic, primary care, urgent care, hospital), has a procedure in place to rapidly and safely isolate a HCID patient or person under investigation (PUI), at least until he/she can be transferred to a better-equipped facility.

- The organization has mechanisms by which it can receive timely and up-to-date information on infectious diseases and outbreak alerts.
- The organization is aware of its role and responsibilities in a HCID event.
- Staff are educated and trained consistent with the facility's response role.
- The organization is aware of which facilities in their region are designated as assessment or treatment centers (as appropriate).
- The organization has plans to coordinate with other facilities in the event that their facility is overwhelmed or otherwise incapacitated by the presence of HCID patients (e.g., due to the contamination of essential equipment).
- The facility has assembled a clearly defined response team—including doctors, nurses, infection control, laboratorians, and support staff—who have received specialized training in personal protective equipment (PPE) and other relevant procedures. Continual training is vital to maintaining proficiency. The level of training may vary by the type of facility (e.g., front-line clinic or hospital, designated assessment hospital, designated treatment center).
- The treatment team for HCID patients may require more personnel than anticipated:
    - Extra personnel may be required to observe PPE donning and doffing procedures.
    - Personnel may be limited in the length of time they can remain in the patient room (e.g., due to required PPE).
    - Staffing specialized treatment teams take personnel away from their normal daily duties, and facilities need a plan to provide surge staffing to supplement their absence.
    - Personnel who are capable of performing a wide range of procedures or duties are extremely valuable on a treatment team, because they may reduce the number of personnel required for patient care.
- The organization has plans for augmenting the response team if needed.
- The facility has designed a monitoring process for clinical personnel exposed to a HCID patient.
- The organization has plans to ensure that personnel who are immersed in the response are adequately supported, including providing meals and accommodations, recoupment of lost wages during the healthcare worker monitoring period, support for family/children/pets, and emotional/mental health services.
- The organization is aware of HCID preparedness training that is available.
    - National Ebola Training & Education Center (NETEC): http://netec.org/

- The organization has reviewed the literature on healthcare workers' willingness to work in disasters and addressed identified issues.[51]
- The organization is prepared to actively reach out to other patients and personnel at the affected facility to reassure them that every effort has been made to ensure their safety in a HCID event. They should be transparent about the known facts, including safety precautions implemented, and provide support to other patients and staff.
- The facility has plans for a treatment and isolation area for HCID patients that enables clinicians to effectively and safely provide care. Considerations for the unit layout include:
    - Patient transport into the area
    - Personnel traffic flow, including PPE donning and doffing areas and one-way traffic flow
    - Necessary equipment and supplies—including PPE storage, required laboratory capabilities, and substitutions for complex equipment (e.g., use of portable ultrasound in place of CT or MRI)
    - Communication with healthcare personnel and the patient
    - Patient bed capacity (may vary by disease)
    - Waste storage and disposal (including autoclave throughput capacity)
    - Ventilation, including negative pressure (patient room vs unit/anteroom, unit vs rest of the facility) and filtration
    - Remote monitoring, including audio/video and patient vital signs
    - Personnel standby/rest areas and locker room/showers

      NOTE: Facilities without dedicated or specially designed isolation/treatment units may not have ideal unit layouts for all of these considerations, and they may have to make concessions in certain areas, keeping patient and healthcare personnel safety in mind.
- The organization has plans for how clinical laboratory testing of HCID patients will be managed. Several options include:
    - Point-of-care testing by the clinical staff within treatment unit
    - Satellite laboratory staffed by laboratorians in the treatment unit or by transport of specimens to a central laboratory located outside of the patient isolation area

      NOTE: These plans must consider the biohazard risks of specimen transport, the risk of equipment contamination, and the risk to the patient of limited access to testing.
- The organization knows how to package and ship specimens to the state public health laboratory for testing of HCID pathogens.

- The organization has a process for determining the level and type of care that will be provided to a HCID patient that balances the moral obligation to provide life-saving treatment to a critically ill patient (e.g., hemodialysis, surgery, CT scans, CPR) with the risks posed to healthcare personnel and/or other patients. The decision-making process for these types of challenges should be applied consistently across city-wide or regional health systems.

  NOTE: Because the particular details for these decisions will vary depending on the disease and the patient's needs, no single specific plan will be applicable for all situations. Rather, the process should include how such resource availability decisions will be made, by whom, and on what basis.

- The organization has a process for determining which equipment can be used for a HCID patient, taking into consideration the risk that the equipment may be temporarily or permanently unavailable due to contamination concerns and the availability of alternative diagnostic/treatment options (e.g., substitute portable ultrasound for MRI/CT scan).

- The organization has a process for determining which types of care and equipment will be made available for individuals who may or may not have the disease such as PUIs or monitored individuals who have a medical condition unrelated to the HCID of concern.

  NOTE: Plans for the care of individuals with possible exposure but without symptoms who require treatment for an unrelated condition (e.g., pregnancy/childbirth, trauma, minor/major surgery) need to be generated in close consultation with relevant personnel and departments in order to provide the necessary level of care required while still properly protecting healthcare providers and other patients.

- The organization has plans for how investigational drugs might be used to combat a HCID for which no licensed drug is available. This includes process for identifying appropriate investigational products and a rapid study design and institutional review board (IRB) approval process. A clinical researcher should be part of the HCID planning team, and a clinical research nurse should be part of the response team.

  NOTE: This also includes having plans in place to address proper informed consent protocols, collection of appropriate specimens and data, and evaluation of other clinical care protocols.

- The organization has plans for no-notice and "mystery patient" drills for emergency departments and other outpatient healthcare facilities.

EMS Checklist

- The EMS agency has developed a designated patient transportation network to be used for infectious disease emergencies. This coordination is especially important for scenarios

that involve multiple different jurisdictions. This network should include representatives from:

  - Public health
  - Health care
  - Law enforcement
  - Other emergency responders (e.g., firefighters)

- Units and personnel participating in the patient transportation network train together in advance of an incident in order to build familiarity with the patient transport procedures as well as everyone else's response protocols. Training and exercises should address a range of transport scenarios, including:
  - Various starting locations (including air/seaports and other healthcare facilities)
  - Known and unknown patients (i.e., notice and no-notice)
  - Secondary/backup treatment and assessment facilities as patient destinations
- The EMS agency has developed a protocol for transferring suspect or confirmed HCID patients.
- The EMS agency has mechanisms by which it can receive timely and up-to-date information on infectious diseases and outbreak alerts.
- The EMS agency has an adequate stockpile of PPE and required supplies and equipment associated with the transportation of HCID patients.
- EMS providers and 9-1-1 dispatchers have a process for rapidly implementing screening protocols for HCIDs.
- EMS providers and 9-1-1 dispatcher have a system of code words to use for radio communications during a HCID event.

Elected Officials Checklist

- The local government has plans for the senior local government official (e.g., mayor, county executive/administrator) to be intimately involved in a HCID response.
- The local government has identified a physician (ideally, an infectious disease physician) to serve as a top advisor to the senior local government official and response leadership (if this role is filled by another individual).
- The state's governor has plans to convene a multidisciplinary expert task force to provide technical and policy advice during a HCID response.

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